UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and THE PEOPLE OF THE STATE OF NEW YORK, by LETITIA JAMES, Attorney General of the State of New York, Plaintiffs, v. QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation; QUINCY BIOSCIENCE, LLC, a limited liability company; PREVAGEN, INC., a corporation d/b/a/ SUGAR RIVER SUPPLEMENTS; QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company; and MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC., Defendants.	Case No. 1:17-cv-00124-LLS

PLAINTIFFS' RESPONSE TO DEFENDANTS' RULE 56.1 STATEMENT AND PLAINTIFFS' STATEMENT OF ADDITIONAL MATERIAL FACTS IN DISPUTE

Pursuant to Federal Rule of Civil Procedure 56 and Local Civil Rule 56.1, Plaintiffs the Federal Trade Commission and the People of the State of New York, by Letitia James, Attorney General of the State of New York, hereby submit the following response to the Rule 56.1 Statement of Material Facts in Support of Defendants' Motion for Summary Judgment (filed April 14, 2022) [Dkt. No.221] and Plaintiffs' Statement of Additional Material Facts in Dispute. Plaintiffs submit that there are genuine issues of material fact that do not entitle

Defendants to judgment as a matter of law. Moreover, certain of Defendants' purported material facts are not, in fact, material or relevant to any issue in this case, and therefore, Plaintiffs intend to challenge the admissibility of Defendants' evidentiary support at the appropriate time.

I. PLAINTIFFS' RESPONSE TO DEFENDANTS' RULE 56.1 STATEMENT

THE COMPLAINT

1. On January 9, 2017, plaintiffs the FTC and NYAG (collectively, "Plaintiffs") filed the Complaint for Permanent Injunction and Other Equitable Relief ("Complaint" or "Compl."). (ECF No. 1.)

RESPONSE: Uncontested.

2. The Complaint challenges the following advertising statements concerning Prevagen: Prevagen improves memory; Prevagen improves memory within 90 days; Prevagen reduces memory problem associated with aging; Prevagen provides other cognitive benefits, including, but not limited to, healthy brain function, a sharper mind, and clearer thinking; and that Prevagen is "clinically shown" to have such effects (collectively, the "Challenged Claims"). (Compl. ¶¶ 36, 39, 42, 44.)

RESPONSE: Uncontested.

THE PARTIES

3. The Federal Trade Commission ("FTC") is an independent agency of the United States Government created by statute. (15 U.S.C. §§ 41-58; Compl. ¶ 6.)

RESPONSE: Uncontested.

4. The People of the State of New York, by Letitia James, Attorney General of the State of New York ("NYAG") bring this action under NY Exec. Law § 63 and NY GBL §§ 349 and 350. (Compl. ¶ 8.)

RESPONSE: Uncontested.

5. Quincy Bioscience Holding Company, Inc. is a Wisconsin corporation with principal place of business in Madison, Wisconsin. (Compl. ¶ 9.)

RESPONSE: Uncontested. Plaintiffs note that Quincy Bioscience Holding Company, Inc.'s full business address is 726 Heartland Trail, Suite 300, Madison, WI. (Compl. ¶ 9.)

6. Quincy Bioscience Holding Company, Inc., wholly owns: Prevagen, Inc., which markets and sells Prevagen Products; Quincy Bioscience Manufacturing, LLC; and Quincy Bioscience, LLC. (ECF 213 ¶¶ 4, 12.)

RESPONSE: Uncontested.

7. Quincy Bioscience, LLC is a Wisconsin limited liability company with its principal place of business in Madison, Wisconsin. (Compl. ¶ 10.)

RESPONSE: Uncontested. Plaintiffs note that Quincy Bioscience LLC's full business address is 726 Heartland Trail, Suite 300, Madison, WI. (Compl. ¶ 10.)

8. Quincy Bioscience Manufacturing, LLC is a Wisconsin limited liability company with its principal place of business in Madison, Wisconsin. (Compl. ¶ 12.)

RESPONSE: Uncontested. Plaintiffs note that Quincy Bioscience Manufacturing, LLC's full business address is 726 Heartland Trail, Suite 300, Madison, WI. (Compl. ¶ 12.)

9. Prevagen, Inc. is a Wisconsin corporation with its principal place of business in Madison, Wisconsin. (Compl. ¶ 11.)

RESPONSE: Uncontested. Plaintiffs note that Prevagen, Inc.'s full business address is 726 Heartland Trail, Suite 300, Madison, WI. (Compl. ¶ 11.)

10. Mark Underwood is the co-founder and President of Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC and Prevagen, Inc. (Compl. ¶ 13; Underwood Decl. ¶ 1.)

RESPONSE: Contested as incomplete. Mark Underwood is the co-founder, President, and Chief Operating Officer of Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., and Quincy Bioscience Manufacturing, LLC, is part of the marketing creative team, directs research programs and activities, and translates scientific data into marketing language. (Soberats Decl. Ex. N, Defs.' Resps. Pls.' First RFAs at 62-63, Nos. 99-100 (Sept. 30, 2020).)

RELEVANT BACKGROUND CONCERNING PREVAGEN

11. Prevagen® is a dietary supplement. (Compl. ¶ 19; ECF 74 ¶ 19; Underwood Decl.¶ 4; Olson Decl. ¶ 4 and Exs. A—F.)

RESPONSE: Contested to the extent that the term, "dietary supplement," has no legal meaning or significance under the FTC Act and New York laws at issue in this case. Food and Drug Administration ("FDA") law and regulations define the term, "dietary supplement;" however, that definition does not apply to, or modify, the FTC Act or New York law governing whether marketing claims are false, misleading, and/or unsubstantiated. Moreover, under FDA law, a product may be either a drug or a dietary supplement depending on how it is marketed. A product sold as a dietary supplement is considered by FDA to be an unapproved drug if it is marketed to diagnose, mitigate, treat, cure, or prevent a disease. 21 U.S.C. § 343(r)(6). In 2012, the FDA issued a warning letter to Mark Underwood, President of Quincy Bioscience Manufacturing, Inc., asserting that the Prevagen products were "being promoted for

conditions that cause these products to be drugs under Section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(g)(1)(B)." (Soberats Decl. Ex. H, FDA warning letter at 1.) The FDA's warning letter further stated that the "therapeutic claims" on Defendants' website establish that the Prevagen products "are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease." (*Id*.) Uncontested to the extent that Prevagen is commonly referred to as a "dietary supplement" in everyday vernacular.

12. Apoaequorin, one of the active ingredients in Prevagen, is a calcium-binding protein derived from aequorin, which was originally discovered in the aequorea victoria jellyfish.(Compl. ¶ 19; Underwood Decl. ¶ 5.)

RESPONSE: Uncontested.

13. The phrase, "dietary supplement," has been on every single bottle of Prevagen that has been sold in the United States since its introduction to the market in 2007. (Olson Decl. ¶ 7 and Exs. A—F.)

RESPONSE: Contested. This fact is irrelevant and immaterial. In addition, Defendants have not produced every package or label of Prevagen sold since 2007.

14. Every package and label of Prevagen sold since 2007 contained the explicit statement that the product "is not intended to diagnose, treat, cure, or prevent any disease." (Compl.Exhibit A ¶ 27 at 10-11; Olson Decl. ¶ 7 and Exs. A—F; Graham Decl. Ex. E, Olson Tr. 172:4- 13.)

RESPONSE: Contested. This fact is irrelevant and immaterial. In addition, Defendants have not produced every package or label of Prevagen sold since 2007.

15. In or around 2016, the Prevagen line of products were reformulated to include

50 micrograms of Vitamin D3. Prevagen Products that contain vitamin D3 contain 50 micrograms of vitamin D3 per capsule or chewable tablet, which is equivalent to 2000 IU of vitamin D. (Underwood Decl. ¶ 8; Graham Decl. Ex. GG, Defendants' Responses and Objections to Plaintiffs' Second Set of Interrogatories dated June 8, 2020, at Response No. 8; Olson Decl. ¶ 10 and Exs. E.)

RESPONSE: Uncontested.

16. Prevagen's target market is, and always has been, healthy, older community dwelling adults who are cognitively normal or who have mild cognitive impairment due to the normal aging process. (Underwood Decl. ¶ 9 and Ex. Q at 2; Graham Decl. Ex. A, Lerner Indiv. Tr. 170:22—171:7; Graham Decl. Ex. B, Lerner 30(b)(6) Tr. 21:16-23, 22:4-11.)

RESPONSE: Contested. Defendants' advertising has included claims that Prevagen is effective in treating or preventing disease. (Soberats Decl. Ex. H, FDA warning letter at 1-5 (QUINCYFTC-547268 to 547272).)

MARKETING AND ADVERTISING OF PREVAGEN

17. Prevagen was first introduced for sale in the United States or around 2007. (Underwood Decl. ¶ 6.)

RESPONSE: Uncontested.

18. Between 2007 and the present, Prevagen has been sold in three different dosages (Regular Strength, Extra Strength, and Professional), two different formats (capsules and chewable tablets), two different sizes (30 and 60 count) and multiple different types of packages. (Underwood Decl. ¶ 7.)

RESPONSE: Uncontested.

19. Prevagen products do not have an expiration date. Prevagen is marketed and

sold to consumers and non-consumers including, but not limited to, brick-and-mortar and online retailers, healthcare professionals, and pharmaceutical distributors. (Olson Decl. ¶¶ 9, 11.)

RESPONSE: Uncontested.

20. The labels for Prevagen products have changed numerous times since 2007. (OlsonDecl. ¶ 12 and Exs. A—F.)

RESPONSE: Uncontested.

21. Beginning in or around 2007, the labels for Prevagen products contained the product descriptor "Jellyfish Fight Aging." Prevagen products with labels bearing the product descriptor "Jellyfish Fight Aging" were available for sale starting in September 2007. (Olson Decl. ¶¶ 13—15 and Ex. A.)

RESPONSE: Uncontested.

22. Beginning in or around 2008, the labels for Prevagen products contained the product descriptor: "Brain Cell Protection." Prevagen products with labels bearing the product descriptor "Brain Cell Protection" were available for sale starting in July 2008. (Olson Decl. ¶¶ 17—19 and Ex. B.)

RESPONSE: Uncontested.

23. Beginning in or around 2011, the labels for Prevagen Products contained the product descriptor "Clearer Thinking." Prevagen products with labels bearing the product descriptor "Clearer Thinking" were available for sale starting in January 2011. (Olson Decl. ¶¶ 21—23 and Ex. C.)

RESPONSE: Uncontested.

24. Beginning in or around late 2012, the labels for Prevagen products contained

the product descriptor "Improves Memory." Prevagen products with labels bearing the product descriptor "Improves Memory" were available for sale starting in December 2012. (Olson Decl. ¶¶ 25—27 and Ex. D.)

RESPONSE: Uncontested.

25. In or around 2016, all of the Prevagen Products were reformulated to include Vitamin D3. The labels for each Prevagen Product that contained Vitamin D3 were changed to reflect the fact that the product now contained Vitamin D3. Prevagen Products with labels reflecting the addition of Vitamin D3 were available for sale starting in the fall of 2016. (Olson Decl. ¶¶ 28—30 and Ex. E.)

RESPONSE: Uncontested.

THE ADVERTISING CHALLENGED IN THE COMPLAINT

26. None of the advertisements featured in the Complaint are currently being used in the marketplace in the form challenged in the Complaint. (Olson Decl. ¶ 32.)

RESPONSE: Contested. The phrases, "featured in the Complaint" and "in the form challenged in the Complaint" are vague. The Complaint does not challenge only the advertisements quoted therein or attached thereto. (*See* Compl. ¶¶ 27, 36, 39, 42, 44.) Furthermore, Plaintiffs contend that Defendants' current advertising continues to make the claims challenged in the Complaint. Certain advertising disseminated by Defendants following the settlement in *Collins v. Quincy Bioscience, LLC* has not contained the disclaimer mandated by the settlement agreement in that case. (Ducklow Decl. Attachments 2-3 (Prevagen videos), 4 (quincybioscience.com), 5-6, 8 (Prevagen videos from quincybioscience.com).) Additionally, the disclaimer does not cure the deceptive net impression of Defendants' ads because the disclaimer (1) is insufficiently

prominent and (2) it improperly represents that Defendants' flawed analysis of subgroups from the Madison Memory Study supports the Challenged Claims. (Olson Decl. Ex. F (Prevagen packaging and labeling); Ducklow Decl. Attachments 12-13 (Prevagen videos); Olson Decl. ¶ 40 (disclaimer language mandated by the *Collins* settlement); Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 20, 38, 68-73, 104, 123; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(c), 7-9; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 13-14, 54-56, 59-74, 78(c)-(d); Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 1-3, 5-18, 20-27.)

27. In or around May 2016, the graph featured on the Prevagen package depicted in Exhibit A of the Complaint was removed. (Olson Decl. ¶ 33.)

RESPONSE: Contested as incomplete. While Defendants removed the graph from the Prevagen package, they continued to use the same, or a substantially similar graph, in other advertising, including television ads. (Ducklow Decl. Attachments 10-11 (screenshots from Prevagen television advertisements.)

28. Defendants have no intention of disseminating the graph depicted in Exhibit A of the Complaint in the future in any marketing or advertising material relating to Prevagen without including one of the Qualifiers (defined at ¶ 45) (Olson Decl. ¶ 33.)

RESPONSE: Contested. This is a self-serving statement of Defendants' future intentions regarding advertising. Furthermore, Plaintiffs contend that Defendants' current advertising continues to make the claims challenged in the Complaint. Certain advertising disseminated by Defendants following the settlement in *Collins v. Quincy Bioscience, LLC* has not contained the disclaimer mandated by the settlement agreement in that case. (Ducklow Decl. Attachments 2-3 (Prevagen videos), 4

(quincybioscience.com), 5-6, 8 (Prevagen videos from quincybioscience.com).) Additionally, the disclaimer does not cure the deceptive net impression of Defendants' ads because the disclaimer (1) is insufficiently prominent and (2) it improperly represents that Defendants' flawed analysis of subgroups from the Madison Memory Study supports the Challenged Claims. (Olson Decl. Ex. F (Prevagen packaging and labeling); Ducklow Decl. Attachments 12-13 (Prevagen videos); Olson Decl. ¶ 40 (disclaimer language mandated by the *Collins* settlement); Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 20, 38, 68-73, 104, 123; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(c), 7-9; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 13-14, 54-56, 59-74, 78(c)-(d); Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 1-3, 5-18, 20-27.)

29. The advertisement included as Exhibit B of the Complaint stopped being disseminated in the form challenged in the Complaint. (Olson Decl. ¶ 34.)

RESPONSE: Contested. The phrase, "in the form challenged in the Complaint," is vague. Furthermore, Plaintiffs contend that Defendants' current advertising continues to make the claims challenged in the Complaint. Certain advertising disseminated by Defendants following the settlement in *Collins v. Quincy Bioscience, LLC* has not contained the disclaimer mandated by the settlement agreement in that case. (Ducklow Decl. Attachments 2-3 (Prevagen videos), 4 (quincybioscience.com), 5-6, 8 (Prevagen videos from quincybioscience.com).) Additionally, the disclaimer does not cure the deceptive net impression of Defendants' ads because the disclaimer (1) is insufficiently prominent and (2) it improperly represents that Defendants' flawed analysis of subgroups from the Madison Memory Study supports the Challenged Claims. (Olson Decl. Ex. F (Prevagen packaging and labeling); Ducklow Decl. Attachments 12-13

(Prevagen videos); Olson Decl. ¶ 40 (disclaimer language mandated by the *Collins* settlement); Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 20, 38, 68-73, 104, 123; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(c), 7-9; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 13-14, 54-56, 59-74, 78(c)-(d); Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 1-3, 5-18, 20-27.)

30. Quincy has no intention of disseminating the advertisement depicted in Exhibit B of the Complaint in the future without including one of the Qualifiers. (Olson Decl. ¶ 34.)

RESPONSE: Contested. This is a self-serving statement of Defendants' future intentions regarding advertising. Furthermore, Plaintiffs contend that Defendants' current advertising continues to make the claims challenged in the Complaint. Certain advertising disseminated by Defendants following the settlement in *Collins v. Quincy Bioscience, LLC* has not contained the disclaimer mandated by the settlement agreement in that case. (Ducklow Decl. Attachments 2-3 (Prevagen videos), 4 (quincybioscience.com), 5-6, 8 (Prevagen videos from quincybioscience.com).) Additionally, the disclaimer does not cure the deceptive net impression of Defendants' ads because the disclaimer (1) is insufficiently prominent and (2) it improperly represents that Defendants' flawed analysis of subgroups from the Madison Memory Study supports the Challenged Claims. (Olson Decl. Ex. F (Prevagen packaging and labeling); Ducklow Decl. Attachments 12-13 (Prevagen videos); Olson Decl. ¶ 40 (disclaimer language mandated by the *Collins* settlement); Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 20, 38, 68-73, 104, 123; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(c), 7-9; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 13-14, 54-56, 59-74, 78(c)-(d); Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 1-3, 5-18, 20-27.)

31. The versions of the Prevagen website pages attached as Exhibit C of the Complaint were removed on or about March 2016. Exhibit C of the Complaint is not the current version of the website and has not been since on or about March 2016. (Olson Decl. ¶ 35.)

RESPONSE: Uncontested.

32. Quincy has no intention of disseminating the website page depicted in Exhibit C ofthe Complaint in the future. (Olson Decl. ¶ 35.)

RESPONSE: Contested. This is a self-serving statement of Defendants' future intentions regarding advertising. Furthermore, Plaintiffs contend that Defendants' current advertising continues to make the claims challenged in the Complaint. Certain advertising disseminated by Defendants following the settlement in *Collins v. Quincy Bioscience, LLC* has not contained the disclaimer mandated by the settlement agreement in that case. (Ducklow Decl. Attachments 2-3 (Prevagen videos), 4 (quincybioscience.com), 5-6, 8 (Prevagen videos from quincybioscience.com).) Additionally, the disclaimer does not cure the deceptive net impression of Defendants' ads because the disclaimer (1) is insufficiently prominent and (2) it improperly represents that Defendants' flawed analysis of subgroups from the Madison Memory Study supports the Challenged Claims. (Olson Decl. Ex. F (Prevagen packaging and labeling); Ducklow Decl. Attachments 12-13 (Prevagen videos); Olson Decl. ¶ 40 (disclaimer language mandated by the *Collins* settlement); Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 20, 38, 68-73, 104, 123; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(c), 7-9; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 13-14, 54-56, 59-74, 78(c)-(d); Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 1-3, 5-18, 20-27.)

33. The Fourth Edition of the Brain Health Guide, attached as Exhibit D of the Complaint, was replaced with the Fifth Edition in or about the summer of 2016. (Olson Decl. ¶ 36.)

RESPONSE: Uncontested.

34. The Fourth Edition of the Brain Health Guide is no longer being disseminated by Defendants and Defendants have no intention of disseminating it in the future. (Olson Decl. ¶ 36.)

RESPONSE: Contested. This is a self-serving statement of Defendants' future intentions regarding advertising. Furthermore, Plaintiffs contend that Defendants' current advertising continues to make the claims challenged in the Complaint. Certain advertising disseminated by Defendants following the settlement in *Collins v. Quincy Bioscience, LLC* has not contained the disclaimer mandated by the settlement agreement in that case. (Ducklow Decl. Attachments 2-3 (Prevagen videos), 4 (quincybioscience.com), 5-6, 8 (Prevagen videos from quincybioscience.com).) Additionally, the disclaimer does not cure the deceptive net impression of Defendants' ads because the disclaimer (1) is insufficiently prominent and (2) it improperly represents that Defendants' flawed analysis of subgroups from the Madison Memory Study supports the Challenged Claims. (Olson Decl. Ex. F (Prevagen packaging and labeling); Ducklow Decl. Attachments 12-13 (Prevagen videos); Olson Decl. ¶ 40 (disclaimer language mandated by the *Collins* settlement); Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 20, 38, 68-73, 104, 123; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(c), 7-9; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 13-14, 54-56, 59-74, 78(c)-(d); Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 1-3, 5-18, 20-27.)

35. The infomercial included as Exhibit E of the Complaint began airing in or around June 2013 and stopped airing in or around June 2014. (Olson Decl. ¶ 37.)

RESPONSE: Uncontested.

36. Defendants have no intention of disseminating the infomercial included as ExhibitE of the Complaint (or any other infomercial) in the future. (Olson Decl. ¶ 37.)

RESPONSE: Contested. This is a self-serving statement of Defendants' future intentions regarding advertising. Furthermore, Plaintiffs contend that Defendants' current advertising continues to make the claims challenged in the Complaint. Certain advertising disseminated by Defendants following the settlement in *Collins v. Quincy Bioscience, LLC* has not contained the disclaimer mandated by the settlement agreement in that case. (Ducklow Decl. Attachments 2-3 (Prevagen videos), 4 (quincybioscience.com), 5-6, 8 (Prevagen videos from quincybioscience.com).) Additionally, the disclaimer does not cure the deceptive net impression of Defendants' ads because the disclaimer (1) is insufficiently prominent and (2) it improperly represents that Defendants' flawed analysis of subgroups from the Madison Memory Study supports the Challenged Claims. (Olson Decl. Ex. F (Prevagen packaging and labeling); Ducklow Decl. Attachments 12-13 (Prevagen videos); Olson Decl. ¶ 40 (disclaimer language mandated by the *Collins* settlement); Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 20, 38, 68-73, 104, 123; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(c), 7-9; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 13-14, 54-56, 59-74, 78(c)-(d); Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 1-3, 5-18, 20-27.)

37. The image of the bus depicted in Exhibit F of the Complaint is from the Better Memory Tour. The Better Memory tour occurred beginning in or about 2011. (Olson Decl. ¶

38.)

RESPONSE: Uncontested.

38. The Better Memory Tour has not been active since 2015. Defendants have nointention of resuming it in the future. (Olson Decl. ¶ 38.)

RESPONSE: Contested. This is a self-serving statement of Defendants' future intentions regarding advertising. Furthermore, Plaintiffs contend that Defendants' current advertising continues to make the claims challenged in the Complaint. Certain advertising disseminated by Defendants following the settlement in *Collins v. Quincy Bioscience, LLC* has not contained the disclaimer mandated by the settlement agreement in that case. (Ducklow Decl. Attachments 2-3 (Prevagen videos), 4 (quincybioscience.com), 5-6, 8 (Prevagen videos from quincybioscience.com).) Additionally, the disclaimer does not cure the deceptive net impression of Defendants' ads because the disclaimer (1) is insufficiently prominent and (2) it improperly represents that Defendants' flawed analysis of subgroups from the Madison Memory Study supports the Challenged Claims. (Olson Decl. Ex. F (Prevagen packaging and labeling); Ducklow Decl. Attachments 12-13 (Prevagen videos); Olson Decl. ¶ 40 (disclaimer language mandated by the *Collins* settlement); Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 20, 38, 68-73, 104, 123; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(c), 7-9; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 13-14, 54-56, 59-74, 78(c)-(d); Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 1-3, 5-18, 20-27.)

THE COLLINS CLASS ACTION SETTLEMENT

39. On June 22, 2020 in the matter captioned *Collins, et al. v. Quincy Bioscience, LLC*, No. 1:19-cv-22864-MGC (S.D. Fla.), Quincy Bioscience, LLC, Quincy Bioscience

Holding Company, Inc., Prevagen, Inc., Quincy Bioscience Manufacturing, LLC, Mark Underwood and Michael Beaman entered into a nationwide class action settlement resolving a series of class actions challenging the same marketing claims challenged in this Action. (the "*Collins* Settlement"). (Graham Decl. Ex. HH, *Collins* ECF No. 143-1.)

RESPONSE: Contested. This fact is irrelevant and immaterial. At this time, neither Plaintiff is seeking restitution on behalf of consumers covered by the class action settlement, and therefore, this fact is neither relevant nor material to any issue in this case.

40. The *Collins* Settlement contained the following release:

> "Upon the Effective Date, and except as to such rights or claims as may be created by this Agreement, and in consideration for the Settlement benefits described in this Agreement, Plaintiffs and the Settlement Class fully release and discharge the Settling Defendants, and all of their present and former parent companies, subsidiaries, special purposes entities formed for the purpose of administering this Settlement, shareholders, owners, officers, directors, employees, agents, servants, registered representatives, attorneys, insurers, affiliates, and successors, personal representatives, heirs and assigns, retailers, suppliers, distributors, endorsers, consultants, and any and all other entities or persons upstream and downstream in the production/distribution channels (together, the "Discharged Parties") from all claims, demands, actions, and causes of action of any kind or nature whatsoever, whether at law or equity, known or unknown, direct, indirect, or consequential, liquidated or unliquidated, foreseen or unforeseen, developed or undeveloped, arising under common law, regulatory law, statutory law, or otherwise, whether based on federal, state or local law, statute, ordinance, regulation, code, contract, common law, or any other source, or any claim that Co-Lead Class Counsel, Plaintiffs' Counsel, Class Representatives, Additional Plaintiffs or Settlement Class Members ever had, now have, may have, or hereafter can, shall or may ever have against the Discharged Parties in any court, tribunal, arbitration panel, commission, agency, or before any governmental and/or administrative body, or any other adjudicatory body, on the basis of, arising from, or relating to the claims alleged in the

Action and the Prevagen Actions."

(Graham Decl. Ex. HH, *Collins* ECF 143-1 at 12.)

RESPONSE: Contested. This fact is irrelevant and immaterial. At this time, neither Plaintiff is seeking restitution on behalf of consumers covered by the class action settlement, and therefore, this fact is neither relevant nor material to any issue in this case.

41. The United States District Court for the Southern District of Florida subsequently found the terms of the *Collins* Settlement to be "fair, reasonable, and adequate," and incorporated them into a Preliminary Approval Order and Final Judgment and Order. (Graham Decl. Exs. II, JJ, *Collins* ECF Nos. 158, 200.)

RESPONSE: Contested. This fact is irrelevant and immaterial. At this time, neither Plaintiff is seeking restitution on behalf of consumers covered by the class action settlement, and therefore, this fact is neither relevant nor material to any issue in this case.

42. On November 18, 2020, the United States District Court for the Southern District of Florida entered a Final Order and Judgment with respect to the Collins Settlement. (Olson Decl.¶ 39; Graham Decl. Ex. JJ, *Collins* ECF No. 200.)

RESPONSE: Contested. This fact is irrelevant and immaterial. At this time, neither Plaintiff is seeking restitution on behalf of consumers covered by the class action settlement, and therefore, this fact is neither relevant nor material to any issue in this case.

43. Under the *Collins* Settlement, any person who purchased Prevagen in the United States since it became available for sale in 2007 was entitled to obtain monetary relief

and they were provided with injunctive relief. (Graham Decl. Ex. HH, *Collins* ECF No. 143-1.)

RESPONSE: Contested. This fact is irrelevant and immaterial. At this time, neither Plaintiff is seeking restitution on behalf of consumers covered by the class action settlement, and therefore, this fact is neither relevant nor material to any issue in this case.

44. In exchange, class members released Quincy Bioscience, LLC, Quincy Bioscience Holding Company, Inc., Prevagen, Inc., Quincy Bioscience Manufacturing, LLC, Mark Underwood and Michael Beaman "from all claims, demands, actions, and causes of action of any kind or nature whatsoever" that they "ever had, now have, may have, or hereafter can, shall or may ever have against the [Defendants] in any court, tribunal, arbitration panel, commission, agency, or before any governmental and/or administrative body, or any other adjudicatory body, on the basis of, arising from, or relating to the claims alleged in the Action." (Graham Decl. Ex. HH, *Collins* ECF No. 143-1.)

RESPONSE: Contested. This fact is irrelevant and immaterial. At this time, neither Plaintiff is seeking restitution on behalf of consumers covered by the class action settlement, and therefore, this fact is neither relevant nor material to any issue in this case.

45. As part of the Collins Settlement, Quincy Bioscience, LLC, Quincy Bioscience Holding Company, Inc., Prevagen, Inc., Quincy Bioscience Manufacturing, LLC, Mark Underwood and Michael Beaman agreed to include in marketing relating to Prevagen one of two statements (referred to herein as the "Qualifiers") with the Challenged Claims:

i. Based on a clinical study of subgroups of individuals who were cognitively normal or mildly impaired. This product is not intended to diagnose, treat,

cure,or prevent any disease.

ii. Based on results from two subgroups of individuals who participated in a randomized double blind placebo controlled clinical study. Participants in the two subgroups were cognitively normal or mildly impaired. This product is notintended to diagnose, treat, cure, or prevent any disease.

(Olson Decl. ¶ 40; Graham Ex. HH, *Collins* ECF No. 143-1 at 8.

RESPONSE: Contested. This fact is irrelevant and immaterial. Furthermore, the mere presence of a disclaimer does not necessarily mean that an ad is not deceptive. *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1497 (1st Cir. 1989) ("Disclaimers . . . are not adequate to avoid liability unless they are sufficiently prominent and unambiguous to change the apparent meaning of the claims and to leave an accurate impression."). "A fine-print disclosure at the bottom of a print ad, a disclaimer buried in a body of text, a brief video superscript in a television ad, or a disclaimer that is easily missed on an Internet web site, are not likely to be adequate." (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189210.)

46. Plaintiffs were notified of the *Collins* Settlement and were afforded an opportunity to object, but chose not to voice an objection when they appeared at the final approval hearing. (Graham Decl. Ex. KK, *Collins* ECF No. 162-2.)

RESPONSE: Contested. No attorney for either Plaintiff appeared at the final approval hearing.

47. Plaintiffs filed a letter on the *Collins* docket stating that their lack of objection to the settlement "should not be construed . . . as approval or disapproval." (Graham Decl. Ex. LL, *Collins* ECF No. 188.).

RESPONSE: Contested as incomplete. While Plaintiffs' letter does include the quoted language, it also states that "the absence of a formal brief from the two agencies

on the proposed settlement should not be interpreted as acquiescence to, or approval of, the settlement terms." (Graham Decl. Ex. LL, Plaintiffs' *Collins* letter at 1.) Plaintiffs in their letter stated as well that they continued "to believe that Quincy has not proffered competent and reliable scientific evidence to substantiate memory or other cognitive claims for Prevagen." (*Id.* at 3.)

48. In fact, despite a comprehensive notice plan, only one objection to the *Collins* Settlement was filed by a serial objector. The *Collins* Court dismissed that objection. (Graham Decl. Exs. KK, NN *Collins* ECF Nos. 195 and 162-2.)

RESPONSE: Uncontested.

49. Following approval of the *Collins* Settlement, the Qualifiers were incorporated into all new advertising, labelling and marketing materials for Prevagen that made the marketing claims identified in the *Collins* Settlement. (Olson Decl. ¶ 41.)

RESPONSE: Contested. Plaintiffs contend that certain advertising disseminated by Defendants following the settlement in *Collins v. Quincy Bioscience, LLC* has not contained the disclaimer mandated by the settlement agreement in that case. (Ducklow Decl. Attachments 2-3 (Prevagen videos), 4 (quincybioscience.com), 5-6, 8 (Prevagen videos from quincybioscience.com).) Additionally, the disclaimer does not cure the deceptive net impression of Defendants' ads because the disclaimer (1) is insufficiently prominent and (2) it improperly represents that Defendants' flawed analysis of subgroups from the Madison Memory Study supports the Challenged Claims. (Olson Decl. Ex. F (Prevagen packaging and labeling); Ducklow Decl. Attachments 12-13 (Prevagen videos); Olson Decl. ¶ 40 (disclaimer language mandated by the *Collins* settlement); Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 20, 38, 68-73, 104, 123;

Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(c), 7-9; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 13-14, 54-56, 59-74, 78(c)-(d); Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 1-3, 5-18, 20-27.)

50. None of the marketing claims identified in the *Collins* Settlement are currently being used in the marketplace in the form challenged in the Complaint, as they all contain one of the Qualifiers. (Olson Decl. ¶¶ 33, 44, 45.)

RESPONSE: Contested. The phrase, "in the form challenged in the Complaint," is vague. Furthermore, Plaintiffs contend that Defendants' current advertising continues to make the claims challenged in the Complaint. Certain advertising disseminated by Defendants following the settlement in *Collins v. Quincy Bioscience, LLC* has not contained the disclaimer mandated by the settlement agreement in that case. (Ducklow Decl. Attachments 2-3 (Prevagen videos), 4 (quincybioscience.com), 5-6, 8 (Prevagen videos from quincybioscience.com).) Additionally, the disclaimer does not cure the deceptive net impression of Defendants' ads because the disclaimer (1) is insufficiently prominent and (2) it improperly represents that Defendants' flawed analysis of subgroups from the Madison Memory Study supports the Challenged Claims. (Olson Decl. Ex. F (Prevagen packaging and labeling); Ducklow Decl. Attachments 12-13 (Prevagen videos); Olson Decl. ¶ 40 (disclaimer language mandated by the *Collins* settlement); Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 20, 38, 68-73, 104, 123; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(c), 7-9; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 13-14, 54-56, 59-74, 78(c)-(d); Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 1-3, 5-18, 20-27.)

51. Plaintiffs concede that they are not seeking restitution on behalf of consumers

whose claims were released by the *Collins* Settlement. (Graham Decl. Ex. NN, Pls.' Resps. & Reply Counter-Findings to Defendants' Prop. Findings of Fact, ¶ 113.)

RESPONSE: Contested. Plaintiffs do not take a position on which consumers' claims were released by the *Collins* settlement. The NYAG is not seeking restitution on behalf of consumers covered by the settlement.

PREVAGEN'S CURRENT LABELING AND ADVERTISING

52. In December 2020, the labels for all Prevagen Products were changed to include one of the Qualifiers: "Based on a clinical study of subgroups of individuals who were cognitively normal or mildly impaired." (Olson Decl. ¶ 42.)

RESPONSE: Contested. Defendants have not produced every label for Prevagen Products used since December 2020.

53. Prevagen Products with this Qualifier were available for sale beginning in or around February 2021. (Olson Decl. ¶ 42.)

RESPONSE: Uncontested.

54. As a result of the *Collins* Settlement, Defendants have no intention of disseminating Prevagen Products without including one of the Qualifiers whenever the label uses one of the marketing claims set forth in the *Collins* Settlement agreement. (Olson Decl. ¶ 44; Graham Decl.HH, *Collins* ECF No. 143-1.)

RESPONSE: Contested. This is a self-serving statement of Defendants' future intentions regarding advertising. Furthermore, Plaintiffs contend that Defendants' current advertising continues to make the claims challenged in the Complaint. Certain advertising disseminated by Defendants following the settlement in *Collins v. Quincy Bioscience, LLC* has not contained the disclaimer mandated by the settlement

agreement in that case. (Ducklow Decl. Attachments 2-3 (Prevagen videos), 4 (quincybioscience.com), 5-6, 8 (Prevagen videos from quincybioscience.com).) Additionally, the disclaimer does not cure the deceptive net impression of Defendants' ads because the disclaimer (1) is insufficiently prominent and (2) it improperly represents that Defendants' flawed analysis of subgroups from the Madison Memory Study supports the Challenged Claims. (Olson Decl. Ex. F (Prevagen packaging and labeling); Ducklow Decl. Attachments 12-13 (Prevagen videos); Olson Decl. ¶ 40 (disclaimer language mandated by the *Collins* settlement); Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 20, 38, 68-73, 104, 123; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(c), 7-9; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 13-14, 54-56, 59-74, 78(c)-(d); Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 1-3, 5-18, 20-27.)

55. As a result of the *Collins* Settlement, Defendants have no intention of claiming that Prevagen improves memory, improves memory within 90 days or any other period of time, or reduces memory problems associated with aging in any advertising or marketing materials for Prevagen in the future without including one of the Qualifiers. (Olson Decl. ¶ 45; Graham Decl. HH, *Collins* ECF No. 143-1.)

RESPONSE: Contested. This is a self-serving statement of Defendants' future intentions regarding advertising. Furthermore, Plaintiffs contend that Defendants' current advertising continues to make the claims challenged in the Complaint. Certain advertising disseminated by Defendants following the settlement in *Collins v. Quincy Bioscience, LLC* has not contained the disclaimer mandated by the settlement agreement in that case. (Ducklow Decl. Attachments 2-3 (Prevagen videos), 4 (quincybioscience.com), 5-6, 8 (Prevagen videos from quincybioscience.com).)

Additionally, the disclaimer does not cure the deceptive net impression of Defendants' ads because the disclaimer (1) is insufficiently prominent and (2) it improperly represents that Defendants' flawed analysis of subgroups from the Madison Memory Study supports the Challenged Claims. (Olson Decl. Ex. F (Prevagen packaging and labeling); Ducklow Decl. Attachments 12-13 (Prevagen videos); Olson Decl. ¶ 40 (disclaimer language mandated by the *Collins* settlement); Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 20, 38, 68-73, 104, 123; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(c), 7-9; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 13-14, 54-56, 59-74, 78(c)-(d); Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 1-3, 5-18, 20-27.)

The Dietary Supplement Health & Education Act of 1994 & the FTC Guidance

56. In recognition of the health benefits of dietary supplements, Congress enacted the Dietary Supplement Health & Education Act of 1994 ("DSHEA"), Public Law 103-417, 103rd Congress. (Graham Decl. Ex. I, https://ods.od.nih.gov/About/DSHEA_Wording.aspx.)

RESPONSE: Uncontested.

57. DSHEA amended the Federal Food, Drug, and Cosmetic Act ("FDCA") to establish standards with respect to dietary supplements, and to create a new category of marketing claims for dietary supplements called "structure/function" claims. (Graham Decl. Ex. I, https://ods.od.nih.gov/About/DSHEA_Wording.aspx.)

RESPONSE: Contested. DSHEA created a category of labeling claims for dietary supplements that are not subject to regulations applicable to drugs provided that those claims are substantiated. (Graham Decl. Ex. J at 2-3.)

58. In January 2002, the United States Food and Drug Administration ("FDA") issuedthe "Small Entity Compliance Guide on Structure/Function Claims." (Graham

Decl. Ex. J, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-structurefunction-claims.)

RESPONSE: Uncontested.

59. Following the passage of DSHEA, the FTC issued "Dietary Supplements: An Advertising Guide For Industry" (the "FTC Guidance"). (Graham Decl. Ex. F, FTC Guidance at 1.)

RESPONSE: Uncontested.

60. The FTC Guidance has not been modified or changed since at least 2001. (GrahamDecl. Ex. F, FTC Guidance at 31.)

RESPONSE: Uncontested.

61. The FTC website displaying the Guidance states that it is designed to "explain[] the how-tos of making sure your claims have appropriate scientific support." (Graham Decl. ¶¶ 8— 10; Ex. H, https://www.ftc.gov/business-guidance/advertising-marketing/health-claims.)

RESPONSE: Uncontested.

62. The FTC Guidance was issued to answer the "many questions" DSHEA generated "about the FTC's approach to dietary supplement advertising." (Graham Decl. Ex. F, FTC Guidance at 1.)

RESPONSE: Uncontested.

63. The FTC Guidance is intended to help marketers understand how FTC law applies to the advertising of dietary supplements. (Graham Decl. Ex. F, FTC Guidance; Graham Decl. Ex. DD, Plaintiffs' Responses and Objections to Defendants' First Set of Interrogatories dated August 6, 2021 at Response No. 29.)

RESPONSE: Uncontested.

64. The FTC Guidance states that dietary supplement advertising "must be truthful, not misleading, and substantiated." (Graham Decl. Ex. F, FTC Guidance at 1.)

RESPONSE: Uncontested.

65. The FTC Guidance states that the substantiation standard for dietary supplements is "flexible," requiring only that advertisers of dietary supplements have "competent and reliable scientific evidence" to substantiate their claims. (Graham Decl. Ex. F, FTC Guidance at 3, 9.)

RESPONSE: Contested. The FTC Guidance states, "[i]f an advertiser asserts that it has a certain level of support for an advertised claim, it must be able to demonstrate that the assertion is accurate. Therefore, as a starting point, advertisers must have the level of support that they claim, expressly or by implication, to have." (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189212.)

66. The FTC Guidance defines "competent and reliable scientific evidence" to mean "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area[.]" (Graham Decl. Ex. F, FTC Guidance at 9.)

RESPONSE: Contested. The FTC Guidance defines competent and reliable scientific evidence as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189212.)

67. Under the FTC Guidance, there is no fixed formula for the number or type of studies required for dietary supplement advertising substantiation; nor is there a fixed formula

for more specific protocol parameters like sample size and study duration. (Graham Decl. Ex. F, FTC Guidance at 8, 9.)

RESPONSE: Contested. The FTC Guidance states, "[i]f an advertiser asserts that it has a certain level of support for an advertised claim, it must be able to demonstrate that the assertion is accurate. Therefore, as a starting point, advertisers must have the level of support that they claim, expressly or by implication, to have." (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189212.)

68. Randomized human clinical trials are not required under the FTC Guidance to substantiate dietary supplement marketing claims. (Graham Decl. Ex. F, FTC Guidance at 9-18.)

RESPONSE: Contested. The FTC Guidance states, "[i]f an advertiser asserts that it has a certain level of support for an advertised claim, it must be able to demonstrate that the assertion is accurate. Therefore, as a starting point, advertisers must have the level of support that they claim, expressly or by implication, to have." Additionally, "[w]hen no specific claim about the level of support is made, the evidence needed depends on the nature of the claim. A guiding principle for determining the amount and type of evidence that will be sufficient is what experts in the relevant area of study would generally consider to be adequate." (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189212-13.)

69. The FTC Guidance states that the FTC will consider all forms of competent and reliable scientific research when evaluating substantiation, including, but not limited to, animal studies, *in vitro* studies, epidemiological evidence, and all forms of human studies. (Graham Decl.Ex. F, FTC Guidance at 10.)

RESPONSE: Contested. The FTC Guidance states, "[i]f an advertiser asserts that it has a certain level of support for an advertised claim, it must be able to demonstrate that the assertion is accurate. Therefore, as a starting point, advertisers must have the level of support that they claim, expressly or by implication, to have." Additionally, "[w]hen no specific claim about the level of support is made, the evidence needed depends on the nature of the claim. A guiding principle for determining the amount and type of evidence that will be sufficient is what experts in the relevant area of study would generally consider to be adequate." (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189212-13.)

70. The FTC Guidance states that "[t]he FTC's standard for evaluating substantiation is sufficiently flexible to ensure that consumers have access to information about emerging areas of science." (Graham Decl. Ex. F, FTC Guidance at 8.)

RESPONSE: Uncontested.

71. The FTC Guidance states that "[s]tudies cannot be evaluated in isolation," and thatthe FTC looks to the "totality of the evidence" in evaluating substantiation. (Graham Decl. Ex. F,FTC Guidance at 12, 14.)

RESPONSE: Contested. The Guidance states that "[t]he surrounding context of the scientific evidence is just as important as the internal validity of individual studies. Advertisers should consider all relevant research relating to the claimed benefit of their supplement and should not focus only on research that supports the effect, while discounting research that does not. Ideally, the studies relied on by an advertiser would be largely consistent with the surrounding body of evidence. Wide variation in outcomes of studies and inconsistent or conflicting results will raise serious questions

about the adequacy of an advertiser's substantiation. Where there are inconsistencies in the evidence, it is important to examine whether there is a plausible explanation for those inconsistencies." (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189217.)

72. There is no requirement in the FTC Guidance that a claim regarding a dietary supplement be supported by any specific number of studies. (Graham Decl. Ex. F, FTC Guidanceat 10.)

RESPONSE: Contested. The FTC Guidance states, "[i]f an advertiser asserts that it has a certain level of support for an advertised claim, it must be able to demonstrate that the assertion is accurate. Therefore, as a starting point, advertisers must have the level of support that they claim, expressly or by implication, to have." Additionally, "[w]hen no specific claim about the level of support is made, the evidence needed depends on the nature of the claim. A guiding principle for determining the amount and type of evidence that will be sufficient is what experts in the relevant area of study would generally consider to be adequate." (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189212-13.)

73. The FTC Guidance states that there is no set protocol for how to conduct research that will be acceptable under the substantiation doctrine and that studies cannot be evaluated in isolation. (Graham Decl. Ex. F, FTC Guidance at 12, 14.)

RESPONSE: Contested. The FTC Guidance's definition of competent and reliable scientific evidence refers to evidence that has been "conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." The FTC Guidance also states

that there are "some principles generally accepted in the scientific community to enhance the validity of test results." (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189212, 00189215.) The FTC Guidance states that "[t]he surrounding context of the scientific evidence is just as important as the internal validity of individual studies. Advertisers should consider all relevant research relating to the claimed benefit of their supplement and should not focus only on research that supports the effect, while discounting research that does not. Ideally, the studies relied on by an advertiser would be largely consistent with the surrounding body of evidence. Wide variation in outcomes of studies and inconsistent or conflicting results will raise serious questions about the adequacy of an advertiser's substantiation. Where there are inconsistencies in the evidence, it is important to examine whether there is a plausible explanation for those inconsistencies." (*Id.* at QUI-FTCNY-00189217.)

74. Quincy reviewed, consulted and relied upon the FTC Guidance when considering and creating marketing and advertising claims for Prevagen. (Underwood Decl. ¶ 10.)

RESPONSE: Contested. The fact is unbound by time and vague and ambiguous as it does not identify any specific advertising claim.

75. Quincy has engaged outside counsel to review the available scientific evidence relating to apoaequorin and vitamin D and cognitive function to confirm that the labels and advertisements for Prevagen comply with all applicable laws and regulations, including the Guidance. (Underwood Decl. ¶ 11; Underwood 30(b)(6) Tr. 148:13—21; Underwood Indiv. Tr. 60:6-9, 85:2—86:17.)

RESPONSE: Contested. The fact is unbound by time and vague and ambiguous as it

does not identify any specific advertisement or label. The Guidance is not a law or regulation, but rather a "guide to clarify how long-standing FTC policies and enforcement practices relate to dietary supplement advertising." (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189204.)

76. Quincy's outside counsel has also been involved with the creation, editing, review, clearance, approval, placement and/or dissemination of labels and advertisements for Prevagen. (Underwood Decl. ¶ 12.)

RESPONSE: Contested. The fact is unbound by time and vague and ambiguous as it does not identify any specific label or advertisement.

77. Neither Plaintiff has issued any specific regulation or guidance prohibiting statistical analysis of a subgroup of participants of a clinical study to substantiate efficacy claims for dietary supplement products. (Graham Decl. Ex. EE, Plaintiffs' Supplemental Responses and Objections to Defendants' Requests for Admission dated August 6, 2021, at Response No. 36.)

RESPONSE: Contested. The term, "guidance," is vague and ambiguous. The FTC Guidance states that the purported evidence should "have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189212.) The FTC Guidance also states that "[a]dvertisers should make sure that the research on which they rely is not just internally valid, but also relevant to the specific product being promoted and to the specific benefit being advertised." (*Id.* at QUI-FTCNY-00189219.)

78. Neither Plaintiff has issued any specific regulation or guidance mandating that

statistical significance must be found in the entire population of a clinical study to substantiate efficacy claims for dietary supplement products. (Graham Decl. Ex. EE, Plaintiffs' Supplemental Responses and Objections to Defendants' Requests for Admission dated August 6, 2021, at Response No. 39.)

RESPONSE: Contested. The term, "guidance," is vague and ambiguous. The FTC Guidance states that the purported evidence should "have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189212.) The FTC Guidance also states that "[a]dvertisers should make sure that the research on which they rely is not just internally valid, but also relevant to the specific product being promoted and to the specific benefit being advertised." (*Id.* at QUI-FTCNY-00189219.)

79. Neither Plaintiff has issued any specific regulation or guidance specifying the threshold of statistical significance required to substantiate efficacy claims for dietary supplement products. (Graham Decl. Ex. EE, Plaintiffs' Supplemental Responses and Objections to Defendants' Requests for Admission dated August 6, 2021, at Response No. 59.)

RESPONSE: Contested. The term, "guidance," is vague and ambiguous. The FTC Guidance states that the purported evidence should "have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189212.) The FTC Guidance also states that "[a]dvertisers should make sure that the research on which they rely is not just internally valid, but also relevant to the specific product being promoted and to the specific benefit

being advertised." (*Id.* at QUI-FTCNY-00189219.)

80. Despite issuing the FTC Guidance to industry, Plaintiffs have taken the position inthis case that "[t]he term 'dietary supplement' has no legal meaning or significance under the FTC Act and New York laws at issue in this case." (Graham Decl. Ex. EE, Plaintiffs' Supplemental Responses and Objections to Defendants' Requests for Admission dated August 6, 2021, at Response Nos. 1, 8.)

RESPONSE: Contested. Plaintiffs' position is that the term, "dietary supplement," although commonly used as a descriptive term, has no legal meaning or significance under the FTC Act and New York laws at issue in this case. FTC Guidance was issued "to clarify how long-standing FTC policies and enforcement practices relate to dietary supplement advertising." (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189204.) The NYAG did not issue the FTC Guidance.

81. Plaintiffs have taken the position that "[a]s applied to the claims challenged in this case, competent and reliable scientific evidence means randomized, controlled human clinical studies ('RCTs') that are well-designed, well-conducted, and properly analyzed according to standards generally accepted by experts in the relevant field." (Graham Decl. Ex. EE, Plaintiffs'Supplemental Responses and Objections to Defendants' Requests for Admission dated August 6,2021, at Response Nos. 1, 8.)

RESPONSE: Contested. For the claims alleged in Count II, and certain of the claims in Counts III and IV of the Complaint, Defendants are required to possess the level of support that they claim, expressly or by implication, in advertising to have. (Compl. ¶¶ 39, 42.B, D, F, H, 44.B, D, F, H.)

82. Plaintiffs' experts have stated that a RCT is required to substantiate the

Challenged Claims. (Graham Decl. Ex. T; Soberats Decl. Ex. A, Sano Aff. Report ¶ 28.)

RESPONSE: Contested. Only one of Plaintiffs' experts, Dr. Sano, has stated that an RCT is required to substantiate the Challenged Claims.

SCIENTIFIC SUBSTANTIATION FOR PREVAGEN

ANIMAL STUDIES

83. In or about November 2004, Quincy entered into a research agreement with the Neurophysiology and Behavior Laboratory, University of Wisconsin-Milwaukee (the "Lab"). The Lab has conducted, and continues to conduct, numerous studies on apoaequorin in animal models. (Graham Decl. Ex. FF, Defendants' Fourth Supplemental Responses and Objections to Plaintiffs' First Set of Interrogatories, at Response No. 2; Underwood Decl. ¶¶ 13—15 and Exs. A—L.)

RESPONSE: Contested. The phrase, "numerous studies on apoaequorin in animal models," is vague and ambiguous. Additionally, this fact is irrelevant and immaterial. Studies conducted in animal models are insufficient to substantiate the advertising claims at issue in this case. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 29, 42; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(e), 14-15.)

84. Results of animal and *in vitro* studies performed at the Lab consistently reported that apoaequorin provides a cognitive benefit, including neuroprotective effects. (Graham Decl. Ex. FF, Defendants' Fourth Supplemental Responses and Objections to Plaintiffs' First Set of Interrogatories, at Response No. 2; Underwood Decl. ¶ 14 and Ex. A—M.)

RESPONSE: Contested. The phrase, "Results of animal and *in vitro* studies performed at the Lab," is vague and ambiguous. Additionally, this fact is irrelevant

and immaterial. Studies conducted in animal models are insufficient to substantiate the advertising claims at issue in this case. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 29, 42; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(e), 14-15.) Defendants' in vitro and animal studies, taken as a whole, support the conclusion that apoaequorin cannot survive digestion long enough to have a therapeutic effect. Defendants commissioned a pepsin digestion experiment that demonstrated that apoaequorin is rapidly digested in laboratory conditions that simulate the stomach environment and, thus, would not enter the bloodstream intact to have a therapeutic effect. (Soberats Decl. Ex. L, Berg Aff. Report ¶¶ 15, 17, 25-29.) Defendants also commissioned a rat study in which orally administered apoaequorin was not shown to be present in the brain following oral administration, or to have a protective effect. (*Id*. at ¶¶ 41-46.) Defendants also conducted a canine study in which orally administered apoaequorin was not shown to cross either the gastrointestinal tract or the blood-brain barrier. (*Id.* at ¶¶ 36-40.) Other studies on which Defendants rely did not involve oral administration of apoaequorin and therefore cannot substantiate claims about Prevagen, which is taken orally. (Underwood Decl. Exs. A, C-J, L-M.)

85. Certain results of animal studies performed at the Lab that reported apoaequorin's neuroprotective effects were published in a peer-reviewed journal: Detert JA, et al., *Pretreatment with apoaequorin protects hippocampal CA1 neurons from oxygen-glucose deprivation*, PLos One, 2013; 8(11):e790002. (Graham Decl. Ex. FF, Defendants' Fourth Supplemental Responses and Objections to Plaintiffs' First Set of Interrogatories, at Response No. 2; Underwood Decl. ¶ 16 and Ex. M.)

RESPONSE: Contested. The phrase, "Certain results of animal studies," is vague and

ambiguous. Additionally, this fact is irrelevant and immaterial. Studies conducted in animal models are insufficient to substantiate the advertising claims at issue in this case. Publication in a peer-reviewed journal does not substantiate efficacy claims. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 29, 42; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(e), 14-15; Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189215.) The results referenced by Defendants did not involve oral administration of apoaequorin and therefore cannot substantiate claims about Prevagen, which is taken orally. (Underwood Decl. Ex. M.) Additionally, Defendants' in vitro and animal studies, taken as a whole, support the conclusion that apoaequorin cannot survive digestion long enough to have a therapeutic effect. Defendants commissioned a pepsin digestion experiment that demonstrated that apoaequorin is rapidly digested in laboratory conditions that simulate the stomach environment and, thus, would not enter the bloodstream intact to have a therapeutic effect. (Soberats Decl. Ex. L, Berg Aff. Report ¶¶ 15, 17, 25-29.) Defendants also commissioned a rat study in which orally administered apoaequorin was not shown to be present in the brain following oral administration, or to have a protective effect. (*Id*. at ¶¶ 41-46.) Defendants also conducted a canine study in which orally administered apoaequorin was not shown to cross either the gastrointestinal tract or the blood-brain barrier. (*Id*. at ¶¶ 36-40.) Other studies on which Defendants rely did not involve oral administration of apoaequorin and therefore cannot substantiate claims about Prevagen, which is taken orally. (Underwood Decl. Exs. A, C-J, L.)

CANINE STUDIES

86. In addition to the studies performed by the Lab, Quincy has also sponsored research on apoaequorin through canine models, which reported that apoaequorin provides

beneficial cognitive effects. (Underwood Decl. ¶¶ 17—18 and Exs. N, O; Graham Decl. Exs. D, S, CC, Gortler Tr. 174:14-21; Kurzer Tr. 102:2-10; Underwood 30(b)(6) Tr. 42:20—43:6.)

RESPONSE: Contested. The phrase, "research on apoaequorin through canine models," is vague and ambiguous. Additionally, this fact is irrelevant and immaterial. Studies conducted in animal models are insufficient to substantiate the advertising claims at issue in this case. Plaintiffs' expert, Mary Sano, Ph.D., has opined that the Milgram beagle studies cited by Defendants' experts do not support the claims of efficacy for Prevagen. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 29, 42; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(e), 14-15.) Defendants' in vitro and animal studies, taken as a whole, support the conclusion that apoaequorin cannot survive digestion long enough to have a therapeutic effect. Defendants commissioned a pepsin digestion experiment that demonstrated that apoaequorin is rapidly digested in laboratory conditions that simulate the stomach environment and, thus, would not enter the bloodstream intact to have a therapeutic effect. (Soberats Decl. Ex. L, Berg Aff. Report ¶¶ 15, 17, 25-29.) Defendants also commissioned a rat study in which orally administered apoaequorin was not shown to be present in the brain following oral administration, or to have a protective effect. (*Id.* at ¶¶ 41-46.) Defendants also conducted a canine study in which orally administered apoaequorin was not shown to cross either the gastrointestinal tract or the blood-brain barrier. (*Id.* at ¶¶ 36-40.) Other studies on which Defendants rely did not involve oral administration of apoaequorin and therefore cannot substantiate claims about Prevagen, which is taken orally. (Underwood Decl. Exs. A, C-J, L-M.) Moreover, neither Dr. Gortler nor Dr. Kurzer is qualified to offer testimony regarding the referenced canine research.

87. Results from Quincy's canine studies reporting apoaequorin's beneficial cognitive effects in canines were published in a peer-reviewed journal: N. Milgram et al., *A novel mechanism for cognitive enhancement in aged dogs with the use of a calcium-buffering protein*, Journal of Veterinary Behavior 10 (2015) 217-222 (Underwood ¶ 19 and Ex. O.)

RESPONSE: Contested. The phrase, "Results from Quincy's canine studies reporting apoaequorin's beneficial cognitive effects in canines" is vague and ambiguous. Additionally, this fact is irrelevant and immaterial. Studies conducted in animal models are insufficient to substantiate the advertising claims at issue in this case. Publication in a peer-reviewed journal does not substantiate efficacy claims. Additionally, Plaintiffs' expert, Mary Sano, Ph.D., has opined that the Milgram beagle studies cited by Defendants' experts do not support the claims of efficacy for Prevagen. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 29, 42; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(e), 14-15; Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189215.) This fact is also irrelevant and immaterial because Defendants' in vitro and animal studies, taken as a whole, support the conclusion that apoaequorin cannot survive digestion long enough to have a therapeutic effect. Defendants commissioned a pepsin digestion experiment that demonstrated that apoaequorin is rapidly digested in laboratory conditions that simulate the stomach environment and, thus, would not enter the bloodstream intact to have a therapeutic effect. (Soberats Decl. Ex. L, Berg Aff. Report ¶¶ 15, 17, 25-29.) Defendants also commissioned a rat study in which orally administered apoaequorin was not shown to be present in the brain following oral administration, or to have a protective effect. (*Id*. at ¶¶ 41-46.) Defendants also conducted a canine study in which orally administered apoaequorin was not shown to cross either the gastrointestinal tract

or the blood-brain barrier. (*Id*. at ¶¶ 36-40.) Other studies on which Defendants rely did not involve oral administration of apoaequorin and therefore cannot substantiate claims about Prevagen, which is taken orally. (Underwood Decl. Exs. A, C-J, L-M.)

88. Results from Quincy's canine studies are particularly persuasive given that dogs provide a natural animal model for mild cognitive dysfunction in humans. (Graham Decl. Ex. R,Kurzer Aff. Report ¶ 30.)

RESPONSE: Contested. The phrases, "Results from Quincy's canine studies" and "particularly persuasive" are vague and ambiguous. Additionally, this fact is irrelevant and immaterial. Studies conducted in animal models are insufficient to substantiate the advertising claims at issue in this case. Testing on humans is necessary. Additionally, Plaintiffs' expert, Mary Sano, Ph.D., has opined that the Milgram beagle studies cited by Defendants' experts do not support the claims of efficacy for Prevagen. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 29, 42; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(e), 14-15.) This fact is also irrelevant and immaterial because Defendants' in vitro and animal studies, taken as a whole, support the conclusion that apoaequorin cannot survive digestion long enough to have a therapeutic effect. Defendants commissioned a pepsin digestion experiment that demonstrated that apoaequorin is rapidly digested in laboratory conditions that simulate the stomach environment and, thus, would not enter the bloodstream intact to have a therapeutic effect. (Soberats Decl. Ex. L, Berg Aff. Report ¶¶ 15, 17, 25-29.) Defendants also commissioned a rat study in which orally administered apoaequorin was not shown to be present in the brain following oral administration, or to have a protective effect. (*Id*. at ¶¶ 41-46.) Defendants also conducted a canine study in which orally administered apoaequorin was not shown to

cross either the gastrointestinal tract or the blood-brain barrier. (*Id*. at ¶¶ 36-40.) Other studies on which Defendants rely did not involve oral administration of apoaequorin and therefore cannot substantiate claims about Prevagen, which is taken orally. (Underwood Decl. Exs. A, C-J, L-M.)

OPEN LABEL HUMAN CLINICAL RESEARCH ON PREVAGEN

89. Between approximately May 2008 and January 2009, Quincy conducted an open label clinical trial (the "Open Label Trial") consisting of approximately 55 adult participants to assess the impact of apoaequorin on general health and quality of life, including cognitive function. (Graham Decl. Ex. FF, Defendants' Fourth Supplemental Responses and Objections to Plaintiffs' First Set of Interrogatories, at Response No. 2; Underwood Decl. ¶ 20 and Ex. P at 149862.)

RESPONSE: The term, "clinical," as used, is vague and ambiguous. In addition, this fact is irrelevant and immaterial, as any purported impact of apoaequorin on "general health and quality of life" is not relevant to any issue in this case.

90. Participants in the Open Label Trial received 10 mg of apoaequorin per day over 90 days and responded to a battery of questions from the SF-36 Survey, a standardized measure of health status, and ERA-38 Survey, the purpose of which is to measure changes in expectations regarding aging among older adults. (Graham Decl. Ex. FF, Defendants' Fourth Supplemental Responses and Objections to Plaintiffs' First Set of Interrogatories, at Response No. 2; Underwood Decl. Ex. P at 149865.)

RESPONSE: Contested. This fact, including the phrases "battery of questions" and "a standardized measure of health status," is vague and ambiguous.

91. The Open Label Trial reported a statistically significant benefit on questions

related to cognitive function, fatigue, sleep, and general health for participants. (Graham Decl. Ex. FF, Defendants' Fourth Supplemental Responses and Objections to Plaintiffs' First Set of Interrogatories, at Response No. 2; Underwood Decl. Ex. P at 149865.)

RESPONSE: Contested. The phrases, "statistically significant benefit" and "questions related to cognitive function, fatigue, sleep, and general health," are vague and ambiguous. In addition, within-group change does not constitute proof of benefit or efficacy, as such change could be due to factors other than the treatment. Demonstrating efficacy requires comparison of a treatment to a control. Furthermore, the fact is irrelevant and immaterial, as any purported impact of apoaequorin on fatigue, sleep, or general health is not relevant to any issue in this case. (Soberats Decl. Ex. A, Sano Aff. Report ¶ 36, Soberats Decl. Ex. C, Wittes Aff. Report ¶ 52.)

92. In or about 2014, Sunsho Pharmaceuticals, Ltd. conducted a human clinical trial testing the efficacy of Prevagen on cognitive functioning and quality of sleep. Fifteen men and woman aged forty and above were administered 1 capsule of Prevagen every morning for 30 days. (Graham Decl. Ex. FF, Defendants' Fourth Supplemental Responses and Objections to Plaintiffs' First Set of Interrogatories, at Response No. 2; Underwood Decl. ¶ 32 and Ex. U, QUI-FTCNY- 00096934-00096953 p. 2.)

RESPONSE: Contested. This fact is incomplete. The Sunsho Pharmaceutical Study was a 15-person, open-label, unblinded study in which the subjects took 10 mg of Prevagen per day for 30 days. The study reported serious compliance issues, stating, for example, that only 5 of the 15 subjects took Prevagen every day, as directed. (Soberats Decl. Ex. B, Sano Rebuttal Report ¶ 14(c)-(d).)

93. The Sunsho trial reported that, after 30 days of intake of Prevagen, there was "a

confirmed rise in the score which showed a statistically significant difference from the score before intake" and that "the effect of 'Prevagen' can be considered to be favorable from the viewpoint of its use as a brain supplement." (Underwood Decl. Ex. U; Graham Decl. Ex. Q, Katz Tr. 113:17 - 114:7.)

RESPONSE: Contested. This fact is incomplete. The referenced "score" refers only to the score on the "Memory Match" game reportedly used in the study. Furthermore, the study noted that "the placebo effect and the effect of learning through games are inherent in this score (by doing the same thing over and over again, you acquire the knack of doing it and this pushes up the score) . . . ." (Underwood Decl. Ex. U, Sunsho Pharmaceutical Study at QUI-FTCNY-00096935.)

94. Neither Plaintiffs, nor anyone acting on their behalf, including their experts, have conducted or caused to be conducted any human clinical research involving Prevagen. (Graham Decl. Ex. EE, Plaintiffs' Supplemental Responses and Objections to Defendants' Requests for Admission dated August 6, 2021, at Response No. 17.)

RESPONSE: Contested. This fact is irrelevant and immaterial and constitutes argument regarding the perceived strength of Plaintiffs' case. Defendants are required to have adequate substantiation for the advertising claims being challenged in this case before dissemination. Plaintiffs have the burden of proving that Defendants' purported substantiation is inadequate, and Plaintiffs need not conduct or present clinical studies showing that the product does not work as claimed. *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 959 (N.D. Ill. 2006) (citing *FTC v. Sabal*, 32 F. Supp. 2d 1004, 1008-09 (N.D. Ill. 1998)). Based on their expertise in the relevant fields and consistent with the principles articulated in the competent and reliable scientific standard, Plaintiffs' experts evaluated

the purported scientific substantiation for the claims at issue in this case. (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189206; Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 13-125; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 1-22; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 13-78; Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 1-27; Soberats Decl. Ex. L, Berg Aff. Report ¶¶ 7-55; Soberats Decl. Ex. M, Berg Rebuttal Report ¶¶ 1-36.)

95. Neither Plaintiffs, nor anyone acting on their behalf, including their experts, have conducted or caused to be conducted any human clinical research involving apoaequorin. (Graham Decl. Ex. EE, Plaintiffs' Supplemental Responses and Objections to Defendants' Requests for Admission dated August 6, 2021, at Response No. 18.)

RESPONSE: Contested. This fact is irrelevant and immaterial and constitutes argument regarding the perceived strength of Plaintiffs' case. Defendants are required to have adequate substantiation for the advertising claims being challenged in this case before dissemination. Plaintiffs have the burden of proving that Defendants' purported substantiation is inadequate, and Plaintiffs need not conduct or present clinical studies showing that the product does not work as claimed. *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 959 (N.D. Ill. 2006) (citing *FTC v. Sabal*, 32 F. Supp. 2d 1004, 1008-09 (N.D. Ill. 1998)). Based on their expertise in the relevant fields and consistent with the principles articulated in the competent and reliable scientific standard, Plaintiffs' experts evaluated the purported scientific substantiation for the claims at issue in this case. (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189206; Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 13-125; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 1-22; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 13-78; Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 1-

27; Soberats Decl. Ex. L, Berg Aff. Report ¶¶ 7-55; Soberats Decl, Ex. M, Berg Rebuttal Report ¶¶ 1-36.)

MADISON MEMORY STUDY

96. Between 2009 and 2011, Quincy conducted the Madison Memory Study, a 90-day randomized, double-blind, placebo-controlled study designed "to determine whether Prevagen with apoaequorin (10 mg) improves quantitative measures of cognitive function in community dwelling, older adults." (Compl. ¶ 28; Underwood Decl. ¶ 21 and Ex. Q at 1, 8.) Kenneth C. Lerner, *Madison Memory Study: A Randomized, Double-Blinded, Placebo-Controlled Trial of Apoaequorin in Community-Dwelling, Older Adults*, at 1 (Aug. 1, 2016) ("MMS")

RESPONSE: Contested. The phrase, "quantitative measures of cognitive function in community dwelling, older adults" is vague and ambiguous. In addition, this fact mischaracterizes the design of the Madison Memory Study. The Madison Memory Study was not a double-blind study. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 45, 65-67; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 44-46.)

97. For the Madison Memory Study, 218 adults aged 40 to 95, each with self-reported memory difficulties, were randomly assigned to receive either apoaequorin capsules or placebos, and were instructed to take one capsule per day. (Underwood Decl. ¶ 22 and Ex. Q at 1, 4.)

RESPONSE: Contested. This fact misrepresents the number of participants that were enrolled into the Madison Memory Study. Approximately 273 participants were enrolled in the Madison Memory Study and 211 completed the study. (Soberats Decl. Ex. F, Lerner 8/6 Tr. at 43:6-8, 13-16; Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 55,

91.)

98. Examiners obtained a baseline cognitive score for each participant using an eight- question screening tool called AD8, used to differentiate between adults facing normal cognitive aging and those with early signs of dementia. (Underwood Decl. ¶ 23 and Ex. Q at 1.)

RESPONSE: Contested. The phrases, "adults facing normal cognitive aging" and "those with early signs of dementia" are vague and ambiguous, and it is unclear to which AD8 score(s) each phrase corresponds. This fact misrepresents how the AD8 was administered and what the screening tool is meant to measure. Participants in the Madison Memory Study completed the AD8, an eight-question interview to differentiate adults facing normal cognitive aging from those experiencing cognitive impairment, with possible scores ranging from AD8 0 to AD8 8. (Soberats Decl. Ex. A, Sano Aff. Report ¶ 45.)

99. AD8 scores of 0 to 2 are generally considered reflective of normal aging or "very mild" cognitive impairment—i.e. healthy, older adults. (Underwood Decl. ¶ 24 and Ex. Q at 2, 4.)

RESPONSE: Uncontested.

100. Participants with AD8 scores of 0 to 2 were the target population for the Madison Memory Study. (Underwood Ex. Decl. ¶ 24 and Ex. Q, MMS at 2, 4; Graham Decl. Ex. A, Lerner Indiv. Tr. 124:17-126:2; Graham Decl. Ex. O, Katz Aff. Report ¶ 32; Graham Decl. Ex. W, Schwartz Aff. Report ¶ 67; Graham Decl. Ex. Z, Wei Reb. Report ¶¶ 32-33.)

RESPONSE: Contested. This fact mischaracterizes the design of the Madison Memory Study. Plaintiffs' experts reviewed the study's protocol and concluded that

the intended study population consists of the over 200 adults who completed the study (all adults scoring between a zero to eight on the AD8 screener). (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 44-45, 56-57, 68-73, 78-79, 93-95, 100; Soberats Decl., Ex. B., Sano Rebuttal Report ¶¶ 5-7; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 54-56, 59-62; Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 3(b).) According to Plaintiffs' experts, the Madison Memory Study's protocol neither mentions the AD8 nor refers to any subgroup of the study population. (Underwood Decl. Ex. R, Madison Memory Study Protocol; Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 44-45, 56-57, 68-69, 78; Soberats Decl, Ex. B, Sano Rebuttal Report ¶¶ 5-7; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 54-56, 59-61, Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 3(b); Soberats Decl. Ex. F, Lerner 8/6 Tr. at 64:10-22; Soberats Decl. Ex. G, Lerner 8/7 Tr. at 22:22-23:8, 46:1-6.) The Madison Memory Study's recruitment materials also do not refer to the AD8, let alone AD8 scores between 0 and 2, or any subgroup of adults. (Underwood Decl. Ex. S.)

101. The recruitment materials from the Madison Memory Study were targeted towards healthy, older adults (i.e. those with AD8 scores between 0 and 2). (Underwood Decl. ¶ 29 and Ex. S.)

RESPONSE: Contested. This fact misrepresents what is stated in the Madison Memory Study's recruitment materials. The recruitment materials neither include the phrase, "healthy, older adults" nor refer to the AD8, let alone AD8 scores between 0 and 2. (Underwood Decl. Ex. S.)

102. While Quincy did not exclude any participants based on AD8 score, the Madison Memory Study used an AD8 score of 2 as a cut-off value to discriminate between

those people who are cognitively normal or who have mild or very mild cognitive impairment (AD8 0-2) versus those with higher levels of impairment (AD8 3-8). (Underwood Ex. Decl. ¶ 24 and Ex. Q at 2, 4; Graham Decl. Ex. B, Lerner 30(b)(6). Tr. 66:17—67:13 ; Graham Decl. Ex. O, Katz Aff. Report ¶ 32; Graham Decl. Ex. W, Schwartz Aff. Report ¶ 67; Graham Decl. Ex. Z, Wei Reb. Report ¶¶ 32—33.)

RESPONSE: Contested. This fact mischaracterizes the design of the Madison Memory Study. Plaintiffs' experts reviewed the study's protocol and concluded that the intended study population consists of the over 200 adults who completed the study (all adults scoring between a zero to eight on the AD8 screener). (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 44-45, 56-57, 68-73, 78-79, 93-95, 100; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 5-7; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 54-56, 59-62; Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 3(b).) According to Plaintiffs' experts, the Madison Memory Study's protocol neither mentions the AD8 nor refers to any subgroup of the study population. (Underwood Decl. Ex. R, Madison Memory Study Protocol; Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 44-45, 56-57, 68-69, 78; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 5-7; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 54-56, 59-61, Wittes Rebuttal Report ¶¶ 3(b); Soberats Decl. Ex. F, Lerner 8/6 Tr. at 64:10-22; Soberats Decl. Ex. G, Lerner 8/7 Tr. at 22:22-23:8, 46:1-6.) The Madison Memory Study's recruitment materials also do not refer to the AD8, let alone AD8 scores between 0 and 2, or any subgroup of adults. (Underwood Decl. Ex. S.)

103. The protocol for the Madison Memory listed a planned sample size of 100 participants. (Underwood Ex. Decl. ¶ 25 and Ex. R.)

RESPONSE: Uncontested.

104. The Madison Memory Study included 100 participants who reported an AD8 score of 0-2. The remaining participants in the Madison Memory Study reported AD8 scores higher than 2. (Underwood Ex. Decl. ¶ 26 and Ex. Q at 5.)

RESPONSE: Uncontested.

105. On days zero, eight, 30, 60, and 90, participants completed nine quantitative computerized tests designed to measure several areas of cognitive function. (Underwood Decl. Ex. Q at 1-2.)

RESPONSE: Contested. This fact misstates the number of computerized tests that were administered to Madison Memory Study participants. A tenth Cogstate task, the Set Shifting Test, was administered, but results for that task do not appear to have been reported. (Soberats Decl. Ex. A, Sano Aff. Report ¶ 46.)

106. The nine quantitative computerized tests were selected from the Cogstate Research Battery—a "widely used neuropsychological battery of computerized cognitive tests"—which measured a variety of aspects of cognitive function, including verbal learning, memory, executive function, visual learning, psychomotor function, and working memory. (Compl. Ex. C(12); Underwood Decl. Ex. Q at 1.)

RESPONSE: Uncontested.

107. Quincy decided to analyze the Madison Memory Study participant data based on AD8 scores before the Madison Memory Study commenced. (Graham Decl. Ex. A, Lerner Indiv.Tr. 124:17—126:2; Underwood Decl. ¶ 28.)

RESPONSE: Contested. This fact mischaracterizes the design of the Madison Memory Study. Plaintiffs' experts reviewed the study's protocol and concluded that the intended study population consists of the over 200 adults who completed the study (all

adults scoring between a zero to eight on the AD8 screener). (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 44-45, 56-57, 68-73, 78-79, 93-95, 100; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 5-7; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 54-56, 59-62, Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 3(b).) According to Plaintiffs' experts, the Madison Memory Study's protocol neither mentions the AD8 nor refers to any subgroup of the study population. (Underwood Decl. Ex. R, Madison Memory Study Protocol; Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 44-45, 56-57, 68-69, 78; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 5-7; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 54-56, 59-61; Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 3(b); Soberats Decl. Ex. F, Lerner 8/6 Tr. at 64:10-22; Soberats Decl. Ex. G, Lerner 8/7 Tr. at 22:22-23:8, 46:1-6.) The Madison Memory Study's recruitment materials also do not refer to the AD8, let alone AD8 scores between 0 and 2, or any subgroup of adults. (Underwood Decl. Ex. S.)

108. At the end of 90 days, Quincy analyzed and reported on the data from all 218 participants, as well as a number of subgroups of participants, including the AD8 0-1 and AD8 0-2 study groups that matched the target study population. (Underwood Decl. Ex. Q at 5—6.)

RESPONSE: Contested. This fact misstates the implementation of the Madison Memory Study. [redacted]

[redacted]

109. The Madison Memory Study demonstrated statistically significant results in the AD8 0-1 and AD8 0-2 targeted study groups, which "contain individuals with either minimal or no cognitive impairment, and are the appropriate population for a dietary supplement intended to support people with mild memory loss associated with aging." (Underwood Decl. Ex. Q at 4.)

RESPONSE: Contested. This fact misstates the results of the Madison Memory Study, as the Study did not report any statistically significant results for the AD8 0-1 or AD8 0-2 subgroups. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 20, 96-107, 123; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(c)-(d), 11-12; Soberats Decl. Ex, C, Wittes Aff. Report ¶¶ 14(b)-(c), 59-74, 78(c)-(d); Soberats Decl. Ex. D, Wittes Rebuttal Report ¶ 3(b)-(d).) The phrase, "appropriate population for a dietary supplement intended to support people with mild memory loss associated with aging," is vague and ambiguous and irrelevant to this action. The term, "dietary supplement," has no legal meaning or significance under the FTC Act and New York laws at issue in this case. Food and Drug Administration ("FDA") law and regulations define the term, "dietary supplement;" however, that definition does not apply to, or modify, the FTC Act or New York law governing whether marketing claims are false, misleading, and/or unsubstantiated. Moreover, under FDA law, a product may be either a drug or a dietary

supplement depending on how it is marketed. A product sold as a dietary supplement is considered by FDA to be an unapproved drug if it is marketed to diagnose, mitigate, treat, cure, or prevent a disease. 21 U.S.C. § 343(r)(6). In 2012, the FDA issued a warning letter to Mark Underwood, President of Quincy Bioscience Manufacturing, Inc., asserting that the Prevagen products were "being promoted for conditions that cause these products to be drugs under Section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(g)(1)(B)." (Soberats Decl. Ex. H, FDA warning letter at 1.) The FDA's warning letter further stated that the "therapeutic claims" on Defendants' website establish that the Prevagen products "are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease." (Soberats Decl. Ex. H, FDA warning letter p. 1.)

110. The Madison Memory Study results showed that participants in the treatment group with AD8 scores of 0-2 showed statistically significant improvements as compared to placebo recipients on three different Cogstate tests (Groton Maze Learning, One Card Learning, and Identification) and outperformed the placebo group on four additional tests. (Underwood Decl. Ex. Q at 6—9.)

RESPONSE: Contested. This fact misstates the results of the Madison Memory Study, as the study did not yield any statistically significant results for the AD8 0-2 subgroup. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 20, 96-107, 123; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(c)-(d), 11-12; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 14(b)-(c), 59-74, 78(c)-(d); Soberats Decl. Ex. D, Wittes Rebuttal Report ¶ 3(b)-(d).) None of the nine Cogstate tasks in the AD8 0-2 subgroup yields statistically significant results if an appropriate statistical correction is applied. (Soberats Decl. Ex. C, Wittes Aff. Report ¶¶

65, 71-74.)

111. Madison Memory Study participants in the treatment group with AD8 scores of 0-1 also experienced statistically significant improvements as compared to placebo recipients on three Cogstate tests (Groton Maze Recall, Detection, and One Card Learning) and outperformed the placebo group on four additional tests. (Underwood Decl. Ex. Q at 9.)

RESPONSE: Contested. This fact misstates the results of the Madison Memory Study, as the study did not yield any statistically significant results for the AD8 0-1 subgroup. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 20, 96-107, 123; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(c)-(d), 11-12; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 14(b)-(c), 59-74, 78(c)-(d); Soberats Decl. Ex. D, Wittes Rebuttal Report ¶ 3(b)-(d).) None of the nine Cogstate tasks in the AD8 0-2 subgroup yields statistically significant results if an appropriate statistical correction is applied. (Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 65, 71-74.)

112. The placebo group did not show any statistically significant improvement as compared to the treatment group on any of the Cogstate states in the AD8 0-1 and AD 0-2 subgroups. (Underwood Ex. Q at 6—9.)

RESPONSE: Contested. The phrase "Cogstate states" is unintelligible. This fact describes purported results that would not be deemed statistically valid evidence of efficacy by scientists in the relevant fields. [redacted] Within-group change does not constitute proof of benefit or efficacy, as such change could be due to factors other than the treatment. Demonstrating efficacy requires comparison of a treatment to a control. (Soberats Decl.

Ex. A, Sano Aff. Report ¶¶ 36, 74, 111; Soberats Decl. Ex. C, Wittes Aff. Report ¶ 52.).

113. Because Prevagen is "intended for healthy, non-demented individuals," results from the AD8 0-1 and AD8 0-2 subgroups were considered "the most relevant to the efficacy of the product." (Underwood Decl. Ex. Q at 1; Graham Decl. Ex. B, Lerner 30(b)(6) Tr. 66:5-13.)

RESPONSE: Contested. This fact mischaracterizes the design of the Madison Memory Study. Plaintiffs' experts reviewed the study's protocol and concluded that the intended study population consists of the over 200 adults who completed the study (all adults scoring between a zero to eight on the AD8 screener). (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 44-45, 56-57, 68-73, 78-79, 93-95, 100; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 5-7; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 54-56, 59-62; Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 3(b).) According to Plaintiffs' experts, the Madison Memory Study's protocol neither mentions the AD8 nor refers to any subgroup of the study population. (Underwood Decl. Ex. R, Madison Memory Study Protocol; Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 44-45, 56-57, 68-69, 78; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 5-7; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 54-56, 59-61; Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 3(b); Soberats Decl. Ex. F, Lerner 8/6 Tr. at 64:10-22; Soberats Decl. Ex. G, Lerner 8/7 Tr. at 22:22-23:8, 46:1-6.). The Madison Memory Study's recruitment materials also do not refer to the AD8, let alone AD8 scores between 0 and 2, or any subgroup of adults. (Underwood Decl. Ex. S.)

114. The Madison Memory Study concluded that "Prevagen demonstrated the ability to improve aspects of cognitive function in older participants with either normal cognitive

aging or very mild impairment, as determined by AD8 screening." (Underwood Decl. Ex. Q at 8; Compl. ¶ 29 (acknowledging "positive findings").)

RESPONSE: Contested. The phrase, "ability to improve aspects of cognitive function" is vague and ambiguous. The phrase, "older participants with either normal cognitive aging or very mild impairment," is also vague and ambiguous, as it is unclear to which AD8 score(s) this phrase corresponds. In addition, this fact constitutes a legal conclusion and/or expert opinion rather than a factual assertion. Finally, this fact misstates the results of the Madison Memory Study, as the study did not report any statistically significant results for the AD8 0-1 or AD8 0-2 subgroups. The Madison Memory Study neither shows that Prevagen improves memory or cognition in humans nor supports the Challenged Claims. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 20, 40-107, 121-123; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3, 5-13, 22; Soberats Decl. Ex, C, Wittes Aff. Report ¶¶ 14, 37-78; Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 3-27.)

115. In 2016, *Advances in Mind Body Medicine* published a peer-reviewed paper titled,"Effects of a Supplement Containing Apoaequorin on Verbal Learning in Older Adults in the Community," which reported on a subset of results from the Madison Memory Study (the "*Advances* Publication"). (Underwood Ex. Decl. ¶ 30 and Ex. T.)

RESPONSE: Contested. The phrase, "subset of results from the Madison Memory Study," is vague and ambiguous. The paper, "Effects of a Supplement Containing Apoaequorin on Verbal Learning in Older Adults in the Community," reported on the entire study population, consisting of over 200 adults, and the AD8 0-1, 0-2, and 2-5 subgroups. (Underwood Decl. Ex. T.) In addition, this fact misstates the quality of the

Advances in Mind Body Medicine journal. The Advances in Mind-Body Medicine journal has a low "impact factor." A journal's impact factor is a measure of how often scientists cite to works published in the journal. A low impact factor means the Advances in Mind Body Medicine is rarely cited, suggesting it does not have a strong reputation among scientists. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 81, 84.).

VITAMIN D

116. The Recommended Dietary Intake for Vitamin D is 600 IU/day for people from 1-70 years of age, and 800 IU/day for people over 70 years of age. (Graham Decl. Ex. R, Kurzer Aff. Report ¶ 17.)

RESPONSE: Contested. The fact is vague and ambiguous.

117. The prevalence of vitamin D deficiency in adults in the United States is approximately 40%. (Graham Decl. Ex. R, Kurzer Aff. Report ¶ 59.)

RESPONSE: Contested. The fact is vague and ambiguous.

118. There is a vast body of scientific literature supporting a relationship between vitamin D, which has been part of Prevagen's formulation since 2016, and improved cognitive function. This evidence includes RCTs, meta-analyses, cross-sectional studies, and prospective studies that demonstrate beneficial associations between higher vitamin D *intake* and cognitive function, as well as higher vitamin D *levels* and cognitive function. (Graham Decl. Ex. R, KurzerAff. Report ¶¶ 60-69.)

RESPONSE: Contested. This fact is vague and ambiguous. The phrases, "RCTs, meta-analyses, cross-sectional studies, and prospective studies" and "beneficial associations," are vague and ambiguous. A study that shows an association between vitamin D and cognitive function does not show that vitamin D improves cognitive function in humans.

Vitamin D has not been shown to improve memory or provide any other cognitive benefit in the general adult population. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 114-120; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 16-19.)

119. Animal studies also suggest that vitamin D influences neuronal development, neuroplasticity, neuronal growth, and neuroprotection. (Graham Decl. Ex. R, Kurzer Aff. Report ¶ 60.)

RESPONSE: Contested. This fact is vague and ambiguous. The terms, "animal studies" and "influences," are vague and ambiguous. A study that shows that vitamin D influences neuronal development, neuroplasticity, neuronal growth, and neuroprotection does not show that vitamin D improves cognitive function in humans. Vitamin D has not been shown to improve memory or provide any other cognitive benefit in the general adult population. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 114-120; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 16-19.)

120. Given the prevalence of vitamin D deficiency in adults in the United States and the low levels of vitamin D being consumed by most people, this large body of scientific evidence supplements the research set forth herein on apoaequorin and confirms that the Challenged Claims are supported by competent and reliable scientific evidence. (Graham Decl. Ex. R, Kurzer Aff. Report ¶¶ 58-78.)

RESPONSE: Contested. Vitamin D has not been shown to improve memory or provide any other cognitive benefit in the general adult population. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 114-120; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 16-19.)

THE PARTIES' EXPERTS

121. Quincy's experts have specialties in the relevant fields of internal medicine,

nutrition, neuroscience, dietary supplement substantiation, epidemiology, and biostatistics. (Graham Decl. Ex. M, Alexander Aff. Report ¶¶ 5, 8—16; Graham Decl. Ex. W, Schwartz Aff. Report ¶¶ 18—80; Graham Decl. Ex. R, Kurzer Aff. Report ¶¶ 30—84; Graham Decl. Ex. O, KatzAff. Report ¶¶ 11—37, 50—70; Graham Decl. Ex. Z, Wei Reb. Report ¶¶ 10—55.)

RESPONSE: Contested. The phrase, "dietary supplement substantiation," is not a scientific field and is not a relevant field for the Challenged Claims.

122. Quincy's experts evaluated Quincy's body of scientific substantiation in accordance with the flexible, totality of the evidence approach set forth in the Guidance, and all concluded that the Challenged Claims are substantiated by competent and reliable scientific evidence. (Graham Decl. Ex. M, Alexander Aff. Report ¶¶ 5, 8—16; Graham Decl. Ex. W, Schwartz Aff. Report ¶¶ 18—80; Graham Decl. Ex. R, Kurzer Aff. Report ¶¶ 30—84; Graham Decl. Ex. O, Katz Aff. Report ¶¶ 11—37, 50—70; Graham Decl. Ex. Z, Wei Reb. Report ¶¶ 10—55; Graham Decl. Ex. F, FTC Guidance at 9—18.)

RESPONSE: Contested. Quincy's experts did not evaluate the body of scientific substantiation in accordance with the approach set forth in the FTC Guidance. (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189212-20.)

123. Quincy's experts have confirmed that Quincy has amassed significantly more scientific substantiation than what is typically seen in the dietary supplement industry. (Graham Decl. Ex. W, Schwartz Rebuttal Report ¶¶ 9, 22.)

RESPONSE: Contested. The fact is vague and ambiguous and irrelevant. Under FTC law, several factors determine the appropriate amount and type of substantiation required, including the nature of the claim. (Graham Decl. Ex. F, FTC Guidance at QUI-FTCNY-00189213.)

124. Plaintiffs' experts did not review any aspect of the FTC Guidance in forming their opinions in this Action. (Graham Decl. Ex. N, Berg Tr. 34:8-16; Graham Decl. Ex. BB, Wittes Tr. 33:6-9, 52:18—54:13; Graham Decl. Ex. U, Sano Tr. 36:16-21, 39:21—41:13; Graham Decl. Ex. V, Sano Decl. ¶¶ 2—7.)

RESPONSE: Contested to the extent that this fact is immaterial.

125. Plaintiffs' expert, Jeremy M. Berg, PhD, testified that he was not familiar the Guidance. (Graham Decl. Ex. N, Berg Tr. 34:14-16.)

RESPONSE: Contested to the extent that this fact is immaterial.

126. Plaintiffs' expert, Mary Sano, PhD, testified that she was not familiar with the Guidance. (Graham Decl. Ex. U, Sano Tr. 39:21-24.)

RESPONSE: Contested to the extent that this fact is immaterial.

127. Plaintiffs' expert, Janet Wittes, PhD, testified that she had never viewed the Guidance. (Graham Decl. Ex. BB, Wittes Tr. 52:18—53:14.)

RESPONSE: Contested to the extent this fact is immaterial.

128. Dr. Berg was not familiar with the "competent and reliable scientific evidence" standard that applies to dietary supplement marketing claims when he was deposed. (Graham Decl. Ex. N, Berg Tr. 34:8-16; 90:6-9.)

RESPONSE: Contested to the extent that this fact is immaterial.

129. Dr. Sano was not familiar with the "competent and reliable scientific evidence" standard that applies to dietary supplement marketing claims when she was deposed. (Graham Decl. Ex. U, Sano. Tr. 37:18—38:11, 39:12—41:8; Graham Decl. Ex. V, Sano Decl. ¶¶ 2—7.)

RESPONSE: Contested to the extent that the phrase, "familiar with the 'competent and reliable scientific evidence' standard that applies to dietary supplement marketing

claims," includes expertise on the procedures, conduct, and analysis of scientific evidence generally accepted in the fields of memory, cognitive impairment, neurosciences of aging and dementia, and clinical trial design, on whether the results of scientific evidence are accurate and reliable, and on the type of evidence needed to support the claims at issue in this case. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 13-125; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 1-22.)

130. Dr. Wittes was not familiar with the "competent and reliable scientific evidence" standard that applies to dietary supplement marketing claims when she was deposed. (Graham Decl. Ex. BB, Wittes Tr. 35:19—37:18.)

RESPONSE: Contested to the extent that the phrase, "familiar with the 'competent and reliable scientific evidence' standard that applies to dietary supplement marketing claims," includes expertise on the procedures, conduct, and analysis of clinical trials generally accepted in the field of biostatistics and on whether the results of scientific evidence are accurate and reliable. (Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 13-78; Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 1-27.)

131. Plaintiffs' experts did not review any marketing material for Prevagen, have no experience in marketing, offered no opinion relating to how consumers would interpret or perceive the Challenged Claims, and therefore offer no opinion as to whether the Challenged Claims are "likely to mislead consumers acting reasonably under the circumstance." (Graham Decl. Ex. U Sano Tr. 40:24—41:4, 50:14-24, 54:4-17, 63:3—64:7, 170:2-14, 266:2-7; Graham Decl. Ex. BB, Wittes Tr. 35:12-18, 38:23—39:2, 51:7—52:6; Graham Decl. Ex. N, Berg Tr. 44:3-6, 110:7-24.

RESPONSE: Contested. Under FTC law, a claim is likely to mislead consumers when

it is false or the advertiser lacked a reasonable basis. *FTC v. Alcoholism Cures, Inc.*, No. 3:10–cv–266–J–34JBT, 2011 WL 13137951, at *26 (M.D. Fla. Sept. 16, 2011). Plaintiffs' experts offered opinions that relate to whether the Challenged Claims were likely to mislead. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 13-125; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 1-22; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 13-78; Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 1-27; Soberats Decl. Ex. L, Berg Aff. Report ¶¶ 7-55; Soberats Decl. Ex. M, Berg Rebuttal Report ¶¶ 1-36.)

132. Plaintiffs proffered no expert testimony on consumer perception. (Graham Decl. Ex. U, Sano Tr. 40:24—41:4, 50:7-20, 54:4-17, 63:3—64:7, 170:2-14, 266:2-7; Graham Decl. Ex. BB, Wittes Tr. 35:12-18, 38:23—39:2, 51:7—52:6; Graham Decl. Ex. N, Berg Tr. 44:3-6, 110:7-24.)

RESPONSE: Contested. This fact is irrelevant and immaterial. Where, as in this case, the challenged claims are express or strongly implied, the trier of fact may determine whether advertisements make the challenged claims without expert testimony on consumer perception. *FTC v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 125-28 & n.8 (D. Conn. 2008); *FTC v. Nat'l Urological Grp*, 645 F. Supp. 2d 1167, 1188-89 & n.12 (N.D. Ga. 2008).

133. Plaintiffs proffered no expert testimony regarding the net impression on consumersof any advertisement or marketing material relating to Prevagen. (Graham Decl. Ex. U, Sano Tr. 40:24—41:4, 50:7-20, 54:4-17, 63:3—64:7, 170:2-14, 266:2-7; Graham Decl. Ex. BB, Wittes Tr. 35:12-18, 38:23—39:2, 51:7—52:6; Graham Decl. Ex. N, Berg Tr. 44:3-6, 110:7-24.)

RESPONSE: Contested. This fact is irrelevant and immaterial. Where, as in this case,

the challenged claims are express or strongly implied, the trier of fact may determine whether advertisements make the challenged claims without expert testimony regarding the net impression of any advertisements. *FTC v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 125-28 & n.8 (D. Conn. 2008); *FTC v. Nat'l Urological Grp*, 645 F. Supp. 2d 1167, 1188-89 & n.12 (N.D. Ga. 2008).

134. Plaintiffs proffered no consumer survey evidence that reflects consumers' interpretation of any advertisement or marketing material relating to Prevagen. (Graham Decl. Ex. EE, Plaintiffs' Supplemental Responses and Objections to Defendants' Requests for Admission dated August 6, 2021, at Request Nos. 24-25.)

RESPONSE: Contested. This fact is irrelevant and immaterial. Where, as in this case, the challenged claims are express or strongly implied, the trier of fact may determine whether advertisements make the challenged claims without resorting to extrinsic evidence of consumer interpretations. *FTC v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 125-28 & n.8 (D. Conn. 2008); *FTC v. Nat'l Urological Grp*, 645 F. Supp. 2d 1167, 1188-89 & n.12 (N.D. Ga. 2008).

135. Plaintiffs proffered no expert evidence relating to any aspect of the marketing of Prevagen. (Graham Decl. Ex. U, Sano Tr. 40:24—41:4, 50:14-24, 54:4-17, 63:3—64:7, 170:2-14, 266:2-7; Graham Decl. Ex. BB, Wittes Tr. 35:12-18, 38:23—39:2, 51:7—52:6; Graham Decl. Ex.N, Berg Tr. 44:3-6, 110:7-24.)

RESPONSE: Contested. The issue of whether the Challenged Claims were substantiated under the FTC Act relates to "any aspect of marketing of Prevagen." *FTC v. COORGA Nutraceuticals*, 201 F. Supp. 3d 1300, 1309 (D. Wyo. 2016) (noting that if an advertiser lacks a reasonable basis to substantiate a claim at the time of

dissemination, the advertisement would be deceptive under the FTC Act). Plaintiffs offered expert evidence relating to whether the Challenged Claims were substantiated. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 13-125; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 1-22; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 13-78; Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 1-27; Soberats Decl. Ex. L, Berg Aff. Report ¶¶ 7-55; Soberats Decl. Ex. M, Berg Rebuttal Report ¶¶ 1-36.)

136. Plaintiffs proffered no expert evidence relating to consumers' perception of any aspect of the marketing of Prevagen. (Graham Decl. Ex. U, Sano Tr. 40:24—41:4, 50:14-24, 54:4-17, 63:3—64:7, 170:2-14, 266:2-7; Graham Decl. Ex. BB, Wittes Tr. 35:12-18, 38:23—39:2, 51:7—52:6; Graham Decl. Ex. N, Berg Tr. 44:3-6, 110:7-24.)

RESPONSE: Contested. This fact is irrelevant and immaterial. Where, as in this case, the challenged claims are express or strongly implied, the trier of fact may determine whether advertisements make the challenged claims without resorting to expert evidence of consumer perception. *FTC v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 125-28 & n.8 (D. Conn. 2008); *FTC v. Nat'l Urological Grp*, 645 F. Supp. 2d 1167, 1188-89 & n.12 (N.D. Ga. 2008).

137. Plaintiffs did not provide Dr. Wittes with documents relating to Prevagen's substantiation other than the Madison Memory Study. (Graham Decl. Ex. AA, Wittes Report Ex.B.)

RESPONSE: Contested. Plaintiffs provided Dr. Wittes with documents other than the Madison Memory Study. (Soberats Decl. Ex. C, Wittes Aff. Report Ex. B.)

138. Dr. Sano reviewed Quincy's animal, *in vitro* and open label studies on apoaequorin, but considered them to be irrelevant. (Graham Decl. Ex. T, Sano Aff. Report ¶¶

15, 29, 42.)

RESPONSE: Contested. Dr. Sano considered Quincy's animal, *in vitro*, and open label studies on apoaequorin to not be adequate evidence of efficacy for the Challenged Claims. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 29, 42; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 14-15.)

139. Drs. Sano and Wittes testified that they did not know when any of the analyses for the Madison Memory Study were conducted, in what order the analyses for the Madison Memory Study were conducted, or which Madison Memory Study analyses were planned and which were exploratory. (Graham Decl. Ex. U, Sano Tr. 182:11—189:12; 204:18—210:15; Graham Ex. BB, Wittes Tr. 111:8-16, 114:7—116:9.)

RESPONSE: Contested. This fact misstates Dr. Wittes and Dr. Sano's testimony. In her deposition, Dr. Sano testified that the analysis of the Madison Memory Study's entire population was conducted first, followed by the analyses of the many subgroups. (Soberats Decl. Ex. J, Sano Tr. 186:20-191:3, 204:21-206:23, 204:21-206:23, Exs. 7, 8.) Dr. Wittes opined in her expert reports and in testimony that "[a]fter failing to find a treatment effect for the study population as a whole, the researchers conducted many *post hoc* analyses of the data, looking at multiple, and often overlapping, subgroups of the study population." (Soberats Decl. Ex. K, Wittes Tr. 105:22-116:9; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 14(b), 55, 58-62, 78(b)-(c); Soberats Decl. Ex. D, Wittes Rebuttal Report ¶ 3(b).)

140. Dr. Wittes testified that "[a] post hoc analysis is usually defined as an analyses that is done that has not been prespecified and that is done after whoever is doing the analysis looks at the data." (Graham Decl. Ex. BB, Wittes Tr. 90:19-25.)

RESPONSE: Uncontested, except Dr. Wittes said "analysis," not "analyses." (Soberats Decl. Ex. K, Wittes Tr. 90:22.)

141. Dr. Sano testified that she had not seen any documents setting forth when any subgroup analysis was conducted, and that she assumed they were conducted after the "entire study population" was analyzed. (Graham Decl. Ex. U, Sano Tr. 182:11—189:12; 204:18—210:15.)

RESPONSE: Contested. This fact misstates Dr. Sano's testimony. In her testimony, Dr. Sano cited a statement from Exhibit 8 of in her deposition ("In addition to an analysis of the study's entire population, the current research team segregated participants into analysis groups based on self-reported levels of cognitive impairment"). She testified, "Well, it says 'in addition,' so I assume that they did the overall first and the secondaries after." (Soberats Decl. Ex. J, Sano Tr. 186:20-191:3.)

142. Dr. Wittes testified that she did not know when the AD8 0-1 or AD8 0-2 data analyses were planned, and that she did not know when or in what order any of Quincy's analyses were conducted. (Graham Decl. Ex. BB, Wittes Tr. 111:8-16, 114:7—116:9.)

RESPONSE: Contested. This fact misstates Dr. Wittes' testimony and the expert opinions contained in her expert reports. Dr. Wittes opined in her expert reports and in testimony that "[a]fter failing to find a treatment effect for the study population as a whole, the researchers conducted many *post hoc* analyses of the data, looking at multiple, and often overlapping, subgroups of the study population." (Soberats Decl. Ex. K, Wittes Tr. 105:22-116:9; Soberats Decl. Ex. C, Wittes Aff. Report ¶ 14(b), 55, 58-62, 78(b)-(c); Soberats Decl. Ex. D, Wittes Rebuttal ¶ 3(b).)

143. Subgroup analyses, and even *post hoc* subgroup analyses, are not only

common, but are published in peer-reviewed journals. (Graham Decl. Ex. W, Schwartz Aff. Report ¶¶ 66—68 and Appendix 1; Graham Decl. Ex. O, Katz Aff. Report ¶¶ 62—66.

RESPONSE: Contested. The studies cited by Drs. Katz and Schwartz carefully qualified the exploratory nature of *post hoc* subgroup findings and the need to conduct follow-up confirmatory trials. Many journals limit reporting to prespecified subgroups. (Soberats Decl. Ex. D, Wittes Rebuttal ¶¶ 6, 20.)

ADUHELM

144. On June 7, 2021, the FDA granted accelerated approval for the drug, aducanumab (marketed as Aduhelm) for the treatment of Alzheimer's Disease. (Graham Decl. Ex. K, Pam Belluck, *F.D.A. Panel Declines to Endorse Controversial Alzheimer's Drug*, N.Y. Times (Nov. 16, 2020), https://www.nytimes.com/2020/11/06/health/aducanumab-alzheimers-drug-fda-panel.html; Pam Belluck and Rebecca Robbins, *F.D.A. Approves Alzheimer's Drug Despite Fierce Debate Over Whether It Works*, N.Y. Times (June 7, 2021), https://www.nytimes.com/2021/06/07/health/aduhelm-fda-alzheimers-drug.html.)

RESPONSE: Contested. This fact is irrelevant and immaterial. The allegations in this case are brought under the FTC Act, New York Executive Law, and New York General Business Law, not any law or regulation related to the United States Food & Drug Administration ("FDA"). (Compl. ¶¶ 1, 2.) FDA standards, regulations, and approval processes are not at issue in determining whether Defendants violated the FTC Act, New York Executive Law, and New York General Business Law. *See Bristol-Myers Co. v. FTC*, 738 F.2d 554, 559 (2d Cir. 1984) ("[i]nsofar as FDA requirements and regulations are concerned, they simply do not govern this case."). In addition, Aduhelm is an entirely different product from Prevagen.

145. Aduhelm is intended for the treatment of Alzheimer's Disease, based on an unplanned analysis of a small subgroup of participants from two separate clinical trials including approximately 3,200 total participants. (Graham Decl. Ex. L, *Aducanumab*, LiverTox: Clinical and Research Information on Drug-Induced Liver Injury, National Institute of Diabetes and Digestive and Kidney Diseases (last updated June 9, 2021), https://www.ncbi.nlm.nih.gov/books/NBK571858/.)

RESPONSE: Contested. This fact is irrelevant and immaterial. The allegations in this case are brought under the FTC Act, New York Executive Law, and New York General Business Law, not any law or regulation related to FDA. (Complaint ¶¶ 1, 2.) FDA standards, regulations, and approval processes are not at issue in determining whether Defendants violated the FTC Act, New York Executive Law, and New York General Business Law. *See Bristol-Myers Co. v. FTC*, 738 F.2d 554, 559 (2d Cir. 1984) ("[i]nsofar as FDA requirements and regulations are concerned, they simply do not govern this case."). In addition, Aduhelm is an entirely different product from Prevagen. The phrase, "small subgroup of participants from two separate clinical trials," is vague and ambiguous, as it is unclear to which "subgroup" or "trial" Defendants refer. Finally, this proposed finding mischaracterizes the basis for FDA's accelerated approval of Aduhelm. According to FDA, the accelerated approval of Aduhelm was "based on the surrogate endpoint of reduction of amyloid beta plaque in the brain—a hallmark of Alzheimer's disease." (Soberats Decl. Ex. O, FDA Press Release, *FDA Grants Accelerated Approval for Alzheimer's Drug.*)

146. Both of those clinical trials were terminated early due to the lack of evidence of efficacy and the severe side effects that were being observed in study participants. (Graham

Decl.Ex. X, Schwartz Rebuttal Report ¶¶ 23—26; Graham Decl. Ex. Y, Schwartz Tr. 235:6-13; GrahamDecl. Ex. P, Katz Rebuttal Report ¶¶ 31—36; Graham Decl. Ex. K.)

RESPONSE: Contested. This fact is irrelevant and immaterial. The allegations in this case are brought under the FTC Act, New York Executive Law, and New York General Business Law, not any law or regulation related to FDA. (Complaint ¶¶ 1, 2.) FDA standards, regulations, and approval processes are not at issue in determining whether Defendants violated the FTC Act, New York Executive Law, and New York General Business Law. *See Bristol-Myers Co. v. FTC*, 738 F.2d 554, 559 (2d Cir. 1984) ("[i]nsofar as FDA requirements and regulations are concerned, they simply do not govern this case."). In addition, Aduhelm is an entirely different product from Prevagen. The phrase, "Both of those clinical trials," is vague and ambiguous, as it is unclear to which clinical trials Defendants refer.

PRE-LITIGATION INVESTIGATION AND LITIGATION

147. On or about July 22, 2015, the FTC issued a Civil Investigative Demand to QuincyBioscience Holding Company, Inc. ("CID"). (Underwood Decl. ¶ 33.)

RESPONSE: Uncontested.

148. Defendants produced over 200,000 pages of discovery to the FTC in connection with the CID. (Graham Decl. ¶ 47.)

RESPONSE: Uncontested.

149. Quincy and its counsel participated in meetings with the FTC in connection with the CID. (Underwood Decl. ¶ 34.)

RESPONSE: Uncontested.

150. Defendants produced nearly 200,000 pages of discovery to Plaintiffs in response

to Plaintiffs' document requests in this Action. (Graham Decl. ¶ 48.)

RESPONSE: Uncontested.

151. Plaintiffs took thirteen depositions in this Action. (Graham Decl. ¶ 46.)

RESPONSE: Contested. Plaintiffs took eleven depositions in this Action.

152. The Court previously ordered Plaintiffs to produce a "sampling" of the challenged advertisements that it intended to pursue at trial. (Graham Decl. ¶ 44) (ECF No. 148.)

RESPONSE: Uncontested.

153. In response, Plaintiffs provided a list of over 1,600 pages of marketing material produced in discovery, as well as various categories of additional documents that are not identified by bates number. (Graham Decl. ¶ 45 and Ex. OO, Plaintiffs' Responses to Quincy's Second Set of Interrogatories dated May 19, 2021 and Amended Ex. A.)

RESPONSE: Uncontested. Plaintiffs note that the only listed documents not identified by bates number were the exhibits to the Complaint and documents produced by Defendants themselves.

154. Plaintiffs did not seek a preliminary injunction or a temporary restraining order at any time in this Action. (Graham Decl. ¶ 50.)

RESPONSE: Uncontested.

155. The FTC has not filed a complaint against Defendants pursuant to its administrative process or otherwise pursued an adjudicative proceeding against Defendants, other than this action.(Underwood Decl. ¶ 35.)

RESPONSE: Uncontested.

II. PLAINTIFFS' STATEMENT OF ADDITIONAL MATERIAL FACTS IN DISPUTE

GENUINE ISSUES OF MATERIAL FACTS AS TO WHETHER AN RCT IS NEEDED

1. Plaintiffs' expert, Mary Sano, Ph.D., has opined that establishing the efficacy of an orally administered product like Prevagen for memory and other cognitive benefits requires competent and reliable scientific evidence in the form of at least one randomized, well-controlled, double-blind clinical trial (hereinafter, "RCT") on the actual product, or a substantially similar product, for which the claims are made. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 23-30, 41-42; Soberats Decl. Ex. B, Sano Rebuttal Report ¶ 3(e).)

2. [redacted] (Graham Decl. Ex. P, Katz Rebuttal Report ¶¶ 18-23, 25-26, 29; Graham Decl. Ex. Z, Wei Rebuttal Report ¶¶ 10-16, 51; Graham Decl. Ex. W, Schwartz Aff. Report ¶¶ 7-10; Glenn Decl. Ex. X, Schwartz Rebuttal Report ¶¶ 3-4, 6, 8, 11-17, 19-22, 49-51.)

3. [redacted] (Graham Decl. Ex. P, Katz Rebuttal Report ¶¶ 21, 23, 26, 29; Graham Decl. Ex. X, Schwartz Rebuttal Report ¶¶ 9, 20, 22, 40, 50.)

4. In rendering her opinion as to the required form of evidence to substantiate the Challenged Claims, Dr. Sano drew upon her education and experience as a clinician,

instructor, author, and active researcher in the fields of memory, cognitive impairment, neurosciences of aging and dementia, and clinical trials, and applied the scientific standards that are widely used by experts in these fields. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 14, 27.)

5. Dr. Sano's review of Defendants' research was based on a standard of evidence that conforms to research methods accepted in the relevant scientific community as capable of supporting valid conclusions as to causation. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 23-39.)

6. Plaintiffs' experts, Dr. Sano and Janet Wittes, Ph.D. (who drew upon her education and experience in biostatistics, the design and analysis of RCTs, and the interpretation of data from RCTs and applied the scientific standards that are widely used by experts in these fields), opine that an RCT should have a protocol that is clear and detailed and defines all critical features of an RCT's design and implementation. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 34, 38; Soberats Decl. Ex. C, Wittes Aff. Report ¶ 15.)

7. Drs. Sano and Wittes observe that the protocol must have a clear description of the trial's purpose, the hypotheses to be tested, the experimental and control groups, the procedures to be used, and the way in which the resulting data will be analyzed statistically and clinically. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 34, 38; Soberats Decl. Ex. C, Wittes Aff. Report ¶ 15.)

8. According to Drs. Sano and Wittes, the RCT's execution should adhere closely to the parameters set out in the protocol, as a study that departs from the original protocol raises concerns about reliability and suggests that researchers might have revised parameters or manipulated data, which might yield more favorable results. (Soberats

Decl. Ex. A, Sano Aff. Report ¶ 35; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 15, 31.)

9. [redacted] (Graham Decl. Ex. P, Katz Rebuttal Report ¶¶ 9, 22-26; Graham Decl. Ex. Z, Wei Rebuttal Report ¶¶ 12-17.)

10. Drs. Sano and Wittes explain that while an RCT's protocol may list subgroups of participants with the goal of testing the efficacy of a treatment in those subgroups, to make any formal inferences about specific subgroups, one must prespecify those subgroups in the RCT's protocol. (Soberats Decl. Ex. A, Sano Aff. Report ¶ 38; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(c), 7; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 26-27, 32-34, 55; Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 20, 22.)

11. Drs. Sano and Wittes explain that *post hoc* subgroup findings (or those subgroup findings not prespecified in a study's protocol) should be confirmed in follow-up research of the target population before they can be relied on as valid evidence of a real effect. (Soberats Decl. Ex. A, Sano Aff. Report ¶ 38; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(c), 7; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 26-27, 32-34, 55; Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 20, 22.)

12. [redacted] (Graham Decl. Ex. O, Katz Aff. Report ¶¶ 62-66; Graham Decl. Ex. X, Schwartz Rebuttal Report ¶¶ 37-38; Graham Decl. Ex. W, Schwartz Aff. Report ¶¶ 66-68 and Appendix 1.)

13. Drs. Sano and Wittes stress that an RCT should yield statistically significant results, but [redacted]

[redacted]

(Soberats Decl. Ex. A, Sano Aff. Report ¶ 36; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 23-25; Graham Decl. Ex. Z, Wei Rebuttal Report ¶¶ 20-21.)

14. In addition to being statistically significant, Dr. Sano notes that an RCT's results should also be clinically meaningful; that is, any cognitive benefits should be substantial enough to translate into noticeable improvements in a real-world setting. (Soberats Decl. Ex. A, Sano Aff. Report ¶ 37.)

15. Indeed, some effects that are statistically significant can be so trivial that they are unlikely to translate into any clinically meaningful improvement in cognitive abilities. (Soberats Decl. Ex. A, Sano Aff. Report ¶ 37.)

GENUINE ISSUES OF MATERIAL FACTS AS TO MADISON MEMORY STUDY DESIGN

16. Although the Madison Memory Study's protocol indicated that the study would have 100 adults, approximately 273 participants were enrolled on a rolling basis and 211 completed the study. (Soberats Decl. Ex. F, Lerner 8/6 Tr. at 43:6-8, 13-16; Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 55, 91.)

17. Defendants disagree that 273 participants were enrolled in the Madison Memory Study. (Defs SOF ¶ 97; Soberats Decl. Ex. E, Defs. Resps. & Prop. Counter-Findings Pls. Prop. Findings of Fact p. 56, Resp. No. 113.)

18. At baseline, participants from the Madison Memory Study completed a screener, the AD8 Dementia Screening Interview ("AD8"), themselves without a third-party informant (*e.g.*, participant's family member or caregiver) and without supervision by a trained clinician. The parties' experts disagree as to whether it is preferable that a third-

party informant complete the AD8. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 45, 60-61; Graham Decl. Ex. O, Katz Aff. Report ¶ 21.)

19. The parties disagree as to whether the AD8 is primarily used as a screening tool to detect dementia and is frequently administered in conjunction with a second exam of cognitive function, such as the Mini-Mental State Exam. (Soberats Decl. Ex. A, Sano Aff. Report ¶ 60; Soberats Decl. Ex. E, Defs. Resps. & Prop. Counter-Findings Pls. Prop. Findings of Fact p. 58, Resp. No. 119.)

20. According to Dr. Sano, there appears to be no consistent correlation between participants' AD8 scores and their baseline performance on the Cogstate tasks that were used as primary outcome measures in the Madison Memory Study. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 62-64.)

21. Dr. Sano observes that because of this, participants' AD8 scores do not appear to accurately predict participants' level of mental impairment as reflected in their baseline scores on the Cogstate tasks, and for that reason, Defendants' conclusions about Prevagen's efficacy for populations with different levels of mental impairment are inherently unreliable. (Soberats Decl. Ex. A, Sano Aff. Report ¶ 64.)

22. [redacted] (Soberats Decl. Ex. E, Defs. Resps. & Prop. Counter-Findings Pls. Prop. Findings of Fact p. 58, Resp. No. 120.)

23. [redacted] (Soberats Decl. Ex. A, Sano Aff. Report

¶¶ 52, 56, 68-73, 77-82, 96-101; Soberats Decl. Ex. B, Sano Rebuttal Report ¶ 6; Soberats Decl. Ex. D, Wittes Report ¶¶ 14, 54-55, 59-62; 78.)

24. [redacted] (Graham Decl. Ex. M, Alexander Aff. Report ¶¶ 12, 14.)

25. According to Plaintiffs' experts, the Madison Memory Study was not double-blinded because: (1) the study was partially unblinded twice, as evidenced by Defendants' press releases reporting interim results after day 60 and after the first 100 participants completed the study and (2) [redacted] (Soberats Decl. Ex. G, Lerner 8/7 Tr. at 32:9-23, 134:6-10, 136:22-138:6; Sano Aff. Report ¶¶ 65, 67; Wittes Aff. Report ¶¶ 44-46.)

26. Defendants maintain that the Madison Memory Study was double-blinded. (Defs. SOF ¶ 96.).

27. Plaintiffs' experts reviewed the study's protocol and concluded that the intended study population consists of the over 200 adults who completed the study (all adults scoring between a zero to eight on the AD8 screener) because the protocol neither mentions the AD8 nor refers to any subgroup of the study population. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 44-45, 56-57, 68-73; 78-79; 93-95; 100; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 5-7; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 54-56; 59-62; Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 3(b); Soberats Decl. Ex. F, Lerner 8/6 Tr. at 64:10-22; Soberats Decl. Ex. G, Lerner 8/7 Tr. at 22:22-23:8, 46:1-6.)

28. Defendants' experts believe the Madison Memory Study protocol makes clear that the

intended study population only consists of two overlapping subgroups of 100 participants who had little to no cognitive impairment (adults scoring between a 0-1 on the AD8, and adults scoring between a 0-2 on the AD8). (Defs. SOF ¶ 100.)

GENUINE ISSUES OF MATERIAL FACT AS TO MADISON MEMORY STUDY IMPLEMENTATION

29. According to Defendants, they decided to analyze the Madison Memory Study participant data based on AD8 scores before the Madison Memory Study commenced. (Defs. SOF ¶ 107.)

30. Plaintiffs' experts counter that Defendants did not decide to analyze participant data based on AD8 scores before the Madison Memory Study commenced because neither the protocol nor Defendants' interim analyses reference the AD8. Defendants segregated participants into subgroups based on AD8 scores *only after* the study had been completed. (Underwood Decl. Ex. R, Madison Memory Study Protocol; Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 44-45, 56-57, 68-73; 78-79; 93-95; 100; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 5-7; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 54-56; 59-62; Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 3(b); Soberats Decl. Ex. F, Lerner 8/6 Tr. at 64:10-22; Soberats Decl. Ex. G, Lerner 8/7 Tr. at 22:22-23:8, 46:1-6.)

31. The Madison Memory Study's recruitment materials also do not refer to the AD8 or any subgroup of adults. (Defs. SOF ¶ 101, Underwood Decl. Ex. S.).

32. [redacted] (Soberats Decl. Ex. A, Sano Aff. Report ¶ 70; Soberats Decl. Ex. C, Wittes Aff. Report ¶ 62.)

33. [redacted]

[redacted] (Soberats Decl. Ex. A, Sano Aff. Report ¶ 70; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 55, 62.)

34. [redacted] (Soberats Decl. Ex, A, Sano Aff. Report ¶ 70; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 55, 62.)

GENUINE ISSUES OF MATERIAL FACT AS TO MADISON MEMORY STUDY RESULTS

35. According to Plaintiffs' experts, the main finding of the Madison Memory Study is there were no statistically significant results between the treatment and control groups on any of the Cogstate tasks for the entire study population of the Madison Memory Study, which consisted of over 200 adults, based on a Type I error rate of p less than or equal to 0.05. (Underwood Decl. Ex. Q, Kenneth C. Lerner, *Clinical Trial Synopsis QB-0011: Madison Memory Study: A Randomized, Double-Blinded, Placebo-Controlled Trial of Apoaequorin in Community-Dwelling, Older Adults*, Quincy Bioscience, LLC (Aug. 1, 2016); Soberats Decl. Ex. A, Sano Report ¶¶ 20, 78, 93-95, 122; Soberats Decl. Ex. B, Sano Rebuttal Report ¶ 3(b); Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 14(a), 58, 78(a); Soberats Decl. Ex. D, Wittes Rebuttal Report ¶ 3(a).)

36. [redacted]

[redacted] (Graham Decl. Ex. Z, Wei Rebuttal Report ¶¶ 18-30.)

37. According to Plaintiffs' experts, this analysis on the entire study population is the only one contemplated in the protocol, and by scientific convention, should be the only result from which conclusions about efficacy can be drawn. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 78, 93-95; Soberats Decl. Ex. C, Wittes Aff. Report ¶ 58.)

38. Defendants disagree, noting that because Prevagen is a dietary supplement "intended for healthy, non-demented individuals," results from the AD8 0-1 and AD8 0-2 subgroups were considered "the most relevant to the efficacy of the product." (Defs. SOF ¶ 113.)

39. [redacted] (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 70, 104; Soberats Decl. Ex. C, Wittes Aff. Report 65-66.)

40. Plaintiffs' experts further opine that because Defendants did not apply any statistical correction, they have overstated the statistical significance of their findings for the AD8 0-1 and AD8 0-2 subgroups. (Soberats Decl. Ex. A, Sano Aff. Report ¶ 104; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 65-74.)

41. In fact, Plaintiffs' experts maintain that none of the nine Cogstate tasks in the AD8 0-1 or 0-2 subgroups yields statistically significant results if an appropriate statistical correction is applied. (Soberats Decl. Ex. A, Sano Aff. Report ¶ 104; Soberats Decl. Ex. C, Wittes Report ¶¶ 65-74.)

42. [redacted]

[redacted] (Graham Decl. Ex. O, Katz Aff. Report ¶¶ 57-61; Graham Decl. Ex. R, Kurzer Aff. Report ¶¶ 38-47; Graham Decl. Ex. X, Schwartz Rebuttal Report ¶¶ 6, 18, Graham Decl. Ex. Z, Wei Rebuttal Report ¶¶ 38-43.)

43. The purportedly significant results Defendants report for the AD8 0-1 and 0-2 subgroups are not clinically meaningful, as they do not reflect an improvement in memory. (Soberats Decl. Ex. A, Sano Aff. Report ¶ 105-107.)

44. Only one of the Cogstate tasks that measures memory most directly–Groton Maze Learning – Delayed Recall ("GMR")–yielded a statistically significant result between the treatment and control groups for the AD8 0-1 subgroup based on a Type I error rate of p less than or equal to 0.05, prior to application of a statistical correction. (Soberats Decl. Ex. A, Sano Aff. Report ¶ 105; Soberats Decl. Ex. B, Sano Rebuttal Report ¶ 11(b)-(c).)

45. None of the Cogstate tasks that measure memory most directly–One Back ("ONB"), Two Back ("TWOB"), International Shopping List – Delayed Recall ("ISRL"), and Groton Maze Learning – Delayed Recall ("GMR")–yielded statistically significant results between the treatment and control groups for the AD8 0-2 subgroup based on a Type I error rate of p less than or equal to 0.05. (Soberats Decl. Ex. A, Sano Aff. Report ¶ 105; Soberats Decl. Ex. B, Sano Rebuttal Report ¶ 11(b)-(c).)

46. Plaintiffs' experts contend, and Defendants dispute, that the Madison Memory Study neither shows that Prevagen improves memory or cognition in humans nor supports the Challenged Claims. (Soberats Decl. Ex. A, Sano Report ¶¶ 20, 40-107, 121-123; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3, 5-13, 22; Soberats Decl. Ex. C, Wittes Aff. Report ¶¶ 14, 37-78; Soberats Decl. Ex. D, Wittes Rebuttal Report ¶¶ 3-27; Defs.

SOF ¶¶ 109-115.)

GENUINE ISSUES OF MATERIAL FACT AS TO DEFENDANTS' OTHER RESEARCH

47. Dr. Sano states that the results of Defendants' *in vitro* and animal studies, while a useful preliminary tool to formulate hypotheses and understand possible mechanisms of action, cannot be directly extrapolated to humans. (Soberats Decl. Ex. A, Sano Aff. Report ¶ 29.)

48. Such studies are not necessarily predictive of what will happen in the human body and are not adequate evidence of efficacy absent confirmation in human studies. (Soberats Decl. Ex. A, Sano Aff. Report ¶ 29; Soberats Decl. Ex. B, Sano Rebuttal Report ¶ 3(e).)

49. Dr. Sano has opined that the dog studies cited by Defendants' experts do not support claims of efficacy for Prevagen. (Soberats Decl. Ex. A, Sano Aff. Report ¶¶ 29, 42; Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(e), 14-15.)

50. Defendants' experts disagree with Dr. Sano and conclude that Defendants' *in vitro* and animal studies indicate that Prevagen's active ingredient, apoaequorin, provides cognitive benefits. (Defs. SOF ¶¶ 84, 86, 88.).

51. Dr. Sano opines, and Defendants dispute, that research that lacks a placebo-control, uses only self-reported subjective outcome measures, or examines an effect on animals does not constitute competent and reliable scientific evidence to support the Challenged Claims. (Soberats Decl. Ex. B, Sano Rebuttal Report ¶ 3(e), Defs. SOF ¶¶ 83-93.)

52. According to Dr. Sano, one of Defendants' open-label trials, the Sunsho Pharmaceutical Trial, suffered from significant methodological flaws in that it lacked a placebo control and blinding, contained no reference to a reliable method for measuring cognitive function, and reported serious compliance issues, stating, for example, that only 5 of the

15 subjects took Prevagen every day, as directed. (Soberats Decl. Ex. B, Sano Rebuttal Report ¶ 14(d).)

53. Defendants' experts conclude that the Sunsho Pharmaceutical Trial reported that "the effect of 'Prevagen' can be considered to be favorable from the viewpoint of its use as a brain supplement." (Defs. SOF ¶ 93.)

54. Dr. Sano disagrees with Defendant's expert, Dr. Mindy Kurzer, that the addition of Vitamin D to Prevagen's formula in 2016 would improve memory or provide any other cognitive benefit in aging adults without significant cognitive impairment. (Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3(f), 16-19; Defs. SOF ¶¶ 118-120.)

55. Dr. Sano explains that vast majority of the studies cited by Dr. Kurzer to support her argument that Vitamin D supplementation benefits memory and cognition are observational studies that do not show causation. (Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 16-19; Defs. SOF ¶ 118; Graham Decl. Ex. R, Kurzer Aff. Report ¶¶ 63-78.)

56. Dr. Sano further explains that the seven RCTs that Dr. Kurzer cites to support her argument regarding a positive effect from Vitamin D supplementation do not constitute competent and reliable scientific evidence to support the challenged claims because these studies suffered from significant flaws, reported inconsistent results, and/or involved specific populations, so their findings cannot be extrapolated to a more general population. (Soberats Decl. Ex. B, Sano Rebuttal Report ¶ 18; Graham Decl. Ex. R, Kurzer Aff. Report ¶¶ 72, 74, Tables 3 and 4.)

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